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Attorneys for Defendant
MONSANTO COMPANY

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

EDWIN HARDEMAN,

Plaintiff,

v.

MONSANTO COMPANY AND JOHN DOES 1-50,

Defendant.

Case No.: 3:16-cv-00525-VC

MONSANTO COMPANY'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF ITS MOTION TO DISMISS

[Filed Concurrently With Notice of Motion and and Memorandum of Points and Authorities]

Judge: Vince Chhabria
Courtroom: 4, 17th Floor

Pursuant to Federal Rule of Evidence 201(b), defendant Monsanto Company ("Monsanto") respectfully requests that this Court take judicial notice of the following exhibits attached hereto in support of Monsanto's Motion to Dismiss Plaintiff's First Amended Complaint:

Exhibit A: EPA, Glyphosate: Reregistration Eligibility Decision (RED) Facts (September 1993), *available at* http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf (last visited Feb. 29, 2016).

Exhibit B: EPA, Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180), *available at* https://www.gpo.gov/fdsys/pkg/FR-2002-09-27/pdf/02-24488.pdf (last visited Feb. 29, 2016).

Exhibit C: EPA, Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180), *available at* https://www.gpo.gov/fdsys/pkg/FR-2004-11-10/pdf/04-25098.pdf (last visited Feb. 29, 2016).

Exhibit D: EPA, Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180), *available at* https://www.gpo.gov/fdsys/pkg/FR-2008-12-03/pdf/E8-28571.pdf (last visited Feb. 29, 2016).

Exhibit E: EPA, Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25396, 25398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180), https://www.gpo.gov/fdsys/pkg/FR-2013-05-01/pdf/2013-10316.pdf (last visited Feb. 29, 2016).

Exhibit F: *Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, & Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs, at time stamp 55:05 – 56:20) (statement of Dr. Ronald E. Kleinman, Physician in Chief at Massachusetts General Hospital for Children, at time stamp 2:39:28 – 2:40:01) (2015), *available at* http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4 (last visited Feb. 29, 2016).

Authority for Exhibits A-F: Federal Rule of Evidence 201 permits the Court to

"judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). "The court may take judicial notice at any stage of the proceeding." *Id.* 201(d). Furthermore, this Court and others in the Ninth Circuit have held that "[d]ocuments available through government agency websites are often considered appropriate for judicial notice as documents in the public record not reasonably subject to dispute." *Musgrave v. ICC/Marie Callender's Gourmet Prods. Div.*, No. 14-cv-02006-JST, 2015 WL 510919, at *3 (N.D. Cal. Feb. 5, 2015); *see Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 878-79 (N.D. Cal. 2013) (taking judicial notice of documents published online by the Food and Drug Administration that demonstrated that the FDA had granted premarket approval to a particular device); *Martinez v. Welk Grp., Inc.*, No. 09 CV 2883 MMA (WMc), 2011 WL 90313, at *2 (S.D. Cal. Jan. 11, 2011) ("Courts routinely take judicial notice of state or federal statutes and regulations."); *Paralyzed Veterans of Am. v. McPherson*, No. C 06-4670 SBA, 2008 WL 4183981, at *5 (N.D. Cal. Sept. 9, 2008) (noting that "information on government agency websites . . . have often been treated as proper subjects for judicial notice"); *321 Studios v. Metro Goldwyn Mayer Studios, Inc.*, 307 F. Supp. 2d 1085, 1107 (N.D. Cal. 2004) (taking judicial notice of several Congressional hearings).

Accordingly, Monsanto respectfully requests the Court to take judicial notice of the above-referenced documents.

DATED: March 1, 2016

Respectfully submitted,

/s/ Richard A. Clark

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MONSANTO COMPANY

Exhibit A

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-93-011 September 1993

R.E.D. FACTS

Glyphosate

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for glyphosate.

Use Profile

Glyphosate is a non-selective herbicide registered for use on many food and non-food field crops as well as non-crop areas where total vegetation control is desired. When applied at lower rates, glyphosate also is a plant growth regulator.

Glyphosate is among the most widely used pesticides by volume. It ranked eleventh among conventional pesticides used in the U.S. during 1990-91. In recent years, approximately 13 to 20 million acres were treated with 18.7 million pounds of glyphosate annually. The largest use sites include hay/pasture, soybeans and field corn.

Three salts of glyphosate are used as active ingredients in registered pesticide products. Two of these active ingredients, plus technical grade glyphosate, are contained in the 56 products that are subject to this RED.

The isopropylamine salt, an active ingredient in 53 registered products, is used as a herbicide to control broadleaf weeds and grasses in many food and non-food crops and a variety of other sites including ornamentals, lawns and turf, residential areas, greenhouses, forest plantings and industrial rights-of-way. It is formulated as a liquid, solid or pellet/tablet, and is applied using ground or aerial equipment.

The sodium salt of glyphosate, an active ingredient in two registered pesticide products, is used as a plant growth regulator for peanuts and sugarcane, to modify plant growth and hasten the ripening of fruit. It is applied as a ground spray to peanut fields and as an aerial spray to sugarcane. Preharvest intervals are established for both crops.

The monoammonium salt of glyphosate is an active ingredient in an additional seven herbicide/growth regulator products. This form of glyphosate was initially registered after November 1984, so it is not subject to reregistration or included in this RED. However, in reassessing the existing glyphosate tolerances (maximum residue limits in or on food and feed), EPA included those for the monoammonium salt.

Regulatory History

EPA issued a Registration Standard for glyphosate in June 1986 (NTIS PB87-103214). The Registration Standard required additional phytotoxicity, environmental fate, toxicology, product chemistry and residue chemistry studies. All of the data required have been submitted and reviewed, or were waived.

Human Health Assessment

Toxicity

Glyphosate is of relatively low oral and dermal acute toxicity. It has been placed in Toxicity Category III for these effects (Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). The acute inhalation toxicity study was waived because glyphosate is non-volatile and because adequate inhalation studies with end-use products exist showing low toxicity.

A subchronic feeding study using rats showed blood and pancreatic effects. A similar study with mice showed reduced body weight gains in both sexes at the highest dose levels. A dermal study with rabbits showed slight reddening and swelling of the skin, decreased food consumption in males and decreased enzyme production, at the highest dose levels.

Several chronic toxicity/carcinogenicity studies using rats, mice and beagle dogs resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study. In June 1991, EPA classified glyphosate as a Group E oncogen--one that shows evidence of non-carcinogenicity for humans--based on the lack of convincing evidence of carcinogenicity in adequate studies.

In developmental toxicity studies using pregnant rats and rabbits, glyphosate caused treatment-related effects in the high dose groups including diarrhea, decreased body weight gain, nasal discharge and death.

One reproductive toxicity study using rats showed kidney effects in the high dose male pups; another study showed digestive effects and decreased body weight gain. Glyphosate does not cause mutations.

In one metabolism study with rats, most of the glyphosate administered (97.5 percent) was excreted in urine and feces as the parent compound; less than one percent of the absorbed dose remained in tissues and organs, primarily in bone tissue. Aminomethyl phosphonic acid (AMPA) was the only metabolite excreted. A second study using rats showed that very little glyphosate reaches bone marrow, that it is rapidly eliminated from bone marrow, and that it is even more rapidly eliminated from plasma.

Dietary Exposure

The nature of glyphosate residue in plants and animals is adequately understood. Studies with a variety of plants indicate that uptake of glyphosate or AMPA from soil is limited. The material which is taken up is readily translocated throughout the plant and into its fruit. In animals, most glyphosate is eliminated in urine and feces. Enforcement methods are available to detect residues of glyphosate and AMPA in or on plant commodities, in water and in animal commodities.

85 tolerances have been established for residues of glyphosate and its metabolite, AMPA, in or on a wide variety of crops and crop groups, as well as in many processed foods, animal feed and animal tissues (please see 40 CFR 180.364, 40 CFR 185.3500 and 40 CFR 186.3500). EPA has reassessed the existing and proposed tolerances for glyphosate. Though some adjustments will be needed, no major changes in existing tolerances are required. EPA also has compared the U.S. tolerances with international Codex maximum residue limits (MRLs), and is recommending certain adjustments to achieve greater compatibility.

EPA conducted a dietary risk assessment for glyphosate based on a worst-case risk scenario, that is, assuming that 100 percent of all possible commodities/acreage were treated, and assuming that tolerance-level residues remained in/on all treated commodities. The Agency concluded that the chronic dietary risk posed by glyphosate food uses is minimal.

A reference dose (RfD), or estimate of daily exposure that would not cause adverse effects throughout a lifetime, of 2 mg/kg/day has been proposed for glyphosate, based on the developmental toxicity studies described above.

Occupational and Residential Exposure

Occupational and residential exposure to glyphosate can be expected based on its currently registered uses. However, due to glyphosate's low acute toxicity and the absence of other toxicological concerns (especially carcinogenicity), occupational and residential exposure data are not required for reregistration.

Some glyphosate end-use products are in Toxicity Categories I or II for primary eye irritation or skin irritation. In California, glyphosate ranks high among pesticides causing illness or injury to workers, who report numerous incidents of eye and skin irritation from splashes during mixing and loading.

EPA is not adding any personal protective equipment (PPE) requirements at this time, but any existing PPE label requirements must be retained.

The Worker Protection Standard (WPS) for Agricultural Pesticides (please see 40 CFR 156 and 170) established an interim restricted entry interval (REI) of 12 hours for glyphosate. The Agency has decided to retain this REI as a prudent measure to mitigate risks to workers. During the REI, workers may reenter areas treated with glyphosate only in the few, narrow exceptions allowed in the WPS. The REI applies only to glyphosate uses within the scope of the WPS, so homeowner and commercial uses are not included.

Human Risk Assessment

EPA's worst case risk assessment of glyphosate's many registered food uses concludes that human dietary exposure and risk are minimal. Existing and proposed tolerances have been reassessed, and no significant changes are needed to protect the public.

Exposure to workers and other applicators generally is not expected to pose undue risks, due to glyphosate's low acute toxicity. However, splashes during mixing and loading of some products can cause injury, primarily eye and skin irritation. EPA is continuing to recommend PPE, including protective eye wear, for workers using end-use products that are in Toxicity Categories I or II for eye and skin irritation. To mitigate potential risks associated with reentering treated agricultural areas, EPA is retaining the 12 hour REI set by the WPS.

Environmental Assessment

Environmental Fate

Glyphosate adsorbs strongly to soil and is not expected to move vertically below the six inch soil layer; residues are expected to be immobile in soil. Glyphosate is readily degraded by soil microbes to AMPA, which is degraded to carbon dioxide. Glyphosate and AMPA are not likely to move to ground water due to their strong adsorptive characteristics. However, glyphosate does have the potential to contaminate surface waters due to its aquatic use patterns and through erosion, as it adsorbs to soil particles suspended in runoff. If glyphosate reached surface water, it would not be broken down readily by water or sunlight.

Ecological Effects

Glyphosate is no more than slightly toxic to birds and is practically non-toxic to fish, aquatic invertebrates and honeybees. Due to the presence of a toxic inert ingredient, some glyphosate end-use products must be labeled, "Toxic to fish," if they may be applied directly to aquatic environments. Product labeling does not preclude off-target movement of glyphosate by drift. EPA therefore is requiring three additional terrestrial plant studies to assess potential risks to nontarget plants.

EPA does not expect that most endangered terrestrial or aquatic organisms will be affected by the registered uses of glyphosate. However,

many endangered plants as well as the Houston toad (due to its habitat) may be at risk. EPA is deferring any use modifications or labeling amendments until it has published the Endangered Species Protection Plan and has given registrants guidance regarding endangered species precautionary labeling.

Ecological Effects Risk Assessment

Based on current data, EPA has determined that the effects of glyphosate on birds, mammals, fish and invertebrates are minimal. Under certain use conditions, glyphosate may cause adverse effects to nontarget aquatic plants. Additional data are needed to fully evaluate the effects of glyphosate on nontarget terrestrial plants. Risk reduction measures will be developed if needed, once the data from these studies are submitted and evaluated.

Additional Data Required

EPA is requiring three generic studies (Tier II Vegetative Vigor, Droplet Size Spectrum, and Drift Field Evaluation) which are not part of the target data base and do not affect the reregistration eligibility of glyphosate. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula and revised labeling.

Product Labeling Changes Required

All end-use glyphosate products must comply with EPA's current pesticide product labeling requirements. In addition:

- **Protection of Aquatic Organisms**

Non-Aquatic Uses - End-use products that are not registered for aquatic uses must bear the following label statement:

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters and rinsate.

Aquatic Uses - End-use products registered for aquatic uses must bear the following label statement:

Do not contaminate water when disposing of equipment washwaters and rinsate. Treatment of aquatic weeds can result in oxygen loss from decomposition for dead plants. This loss can cause fish kills.

- **Worker Protection Standard (WPS) Requirements**

Any product whose labeling permits use in the production of an agricultural plant on any farm, forest, nursery or greenhouse must comply with the labeling requirements of:

- PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and

- PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7."

Unless specifically directed in the RED, all statements required by these two PR Notices must appear on product labeling exactly as instructed in the Notices. Labels must be revised by April 21, 1994, for products distributed or sold by the primary registrant or supplementally registered distributors, and by October 23, 1995, for products distributed or sold by anyone.

- **Personal Protective Equipment (PPE)**

No new PPE requirements must be added to glyphosate labels. However, any existing PPE requirements on labels must be retained.

- **Entry Restrictions**

Products Not Primarily Intended for Home Use:

- Uses Within the Scope of the WPS - A 12-hour restricted entry interval (REI) is required for all products with uses within the scope of the WPS, except products intended primarily for home use. The PPE for early entry should be that required for applicators of glyphosate, except any applicator requirement for an apron or respirator is waived. This REI and PPE should be inserted into the standardized statements required by PR Notice 93-7.
  - Sole Active Ingredient End-Use Products - Labels must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed.
  - Multiple Active Ingredient Products - Registrants must compare the entry restrictions set forth in this section to those on their current labeling and retain the more protective. A specific time period in hours or days is considered more protective than "until sprays have dried" or "dusts have settled."

- Uses Not Within the Scope of the WPS - No new entry restrictions must be added. However, any entry restrictions on current product labeling with these uses must be retained.

Products Primarily Intended for Home Use:

- No new entry restrictions must be added. However, any entry restrictions on current product labeling must be retained.

Regulatory Conclusion

The use of currently registered pesticide products containing the isopropylamine and sodium salts of glyphosate in accordance with the labeling specified in this RED will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These glyphosate products will be reregistered once the required product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products which contain active ingredients in addition to glyphosate will not be reregistered until all their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for glyphosate during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703- 305-5805.

Following the comment period, the glyphosate RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the glyphosate RED, or reregistration of individual products containing glyphosate, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.

Exhibit B

Commodity	Parts per million	Expiration/ Revocation Date
* *	*	* *
Beet, sugar, molasses	0.75	None
* *	*	* *
Caneberry subgroup	0.70	None
* *	*	* *
Cattle, fat	6.5	None
Cattle, meat	0.50	None
Cattle, meat byproducts	2.0	None
* *	*	* *
Fig	0.10	None
* *	*	* *
Grape	0.50	None
Grape, raisin	0.70	None
* *	*	* *
Herb, dried, subgroup	22	None
Herb, fresh, subgroup	3.0	None
* *	*	* *
Milk	2.5	None
Milk, fat	27	None
* *	*	* *
Peanut	0.02	None
* *	*	* *
Vegetable, root and tuber, group	0.10	None
* *	*	* *

* * * * *

[FR Doc. 02–24484 Filed 9–26–02; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0232; FRL–7200–2]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glyphosate in or on animal feed, nongrass group; grass, forage, fodder and hay, group and adds the potassium salt of glyphosate to the tolerance expression. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0232, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0232 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins (PM 25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: *Tompkins.Jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homp page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0232. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background

In the **Federal Register** of April 17, 2002 (FR 67 18894) (FRL–6830–5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 0F06130, 0F06195, and 0F06273) by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005.

The notice included a summary of the petition prepared by Monsanto, the registrant. Comments received in the public docket with respect to the Notice of Filing Pesticide Petitions to Establish a Tolerance for Glyphosate in or on Food (April 17, 2002, 67 FR 18894) are discussed in the section below.

III. Response to Comments

The Northwest Coalition for Alternatives to Pesticides (NCAP) researches and cites studies that are not included in corporate evaluations of their products, and summarizes them in the Journal of Pesticide Reform. The following comments submitted to the Agency by Jill Davies/RiverCare, Martha T. Franks/Taylor Farms and Jeff Schahczenski/Executive Director/ Western Sustainable Agriculture Working Group cite the opinions of the NCAP concerning the information contained within the April 17, 2002 **Federal Register** for glyphosate.

A. Residue Chemistry

The Notice states:

1. *Plant metabolism*. The nature of the residue in plants is adequately understood and consists of the parent, glyphosate and its metabolite aminomethyl-phosphonic acid (AMPA). Only the glyphosate parent is to be regulated in plant and animal commodities since the metabolite AMPA is not of toxicological concern in food.

Comment: The metabolite AMPA is of toxicological concern. In subchronic (midterm) tests on rats, AMPA caused an increase in the activity of an enzyme, lactic dehydrogenase, in both sexes; a decrease in liver weights in males at all doses tested; and excessive cell division in the lining of the urinary bladder in both sexes.

Agency response. The subchronic toxicity of AMPA has been investigated in rats and dogs. Treatment-related effects, such as urinary tract irritation, were observed in rats only at very high dosage levels. Gross and histopathologic examinations of these animals did not reveal effects in any other organ. No toxicities occurred in dogs at any dosage level tested. Based on these results, the Agency concluded that the metabolite of glyphosate, AMPA, is not of toxicological concern because the effects observed in subchronic toxicity studies cited above were: (1) Not dose-related, and/or (2) not considered biologically significant.

Comment: The mode of action of the residue in plants is not adequately understood. It is known that glyphosate is a systemic and non-selective herbicide that kills grasses, sedges, and broad-leaved plants, but exactly how it works is not well understood.

Agency response. Residue chemistry/ plant metabolism studies for pesticidal active ingredients are not designed to determine the mode-of-action in plants, but instead are designed to determine the metabolic fate, including the identification of plant metabolites of the active ingredient, when it is systemically present in plants.

Although not relevant to nature of the residue studies, the primary mode of action for glyphosate is well understood and documented. Glyphosate is a member of the phosphono amino acid class of chemicals. These compounds are foliar-applied herbicides that interfere with normal plant amino acid synthesis, resulting in the inhibition of nucleic acid metabolism and protein synthesis. Specifically, glyphosate blocks the activity of 5-enolpyruvylshikimate 3-phosphate synthase (EPSP synthase), an enzyme that is involved in aromatic amino acid biosynthesis (essential for growth) and produced only by green plants. This pathway does not occur in animals, which must eat plants to obtain these essential amino acids. Consequently, glyphosate is toxic to all green plants and essentially nontoxic to other living organisms.

B. Toxicological Profile

The Notice states:

1. *Acute toxicity*. Several acute toxicology studies place technical-grade glyphosate in Toxicity Category III and Toxicity Category IV.

Comment: This is correct, and Toxicity Category III means caution. But most toxicology studies are conducted using glyphosate alone, not the formulations that are in commercial products, which contain so-called inert ingredients. Roundup, which contains glyphosate and the surfactant POEA, is three times as acutely toxic to rats as glyphosate alone. This deficiency in regulation needs to be corrected.

Agency response. This action establishes a tolerance for glyphosate, not the inert polyethylated tallow amines (POEA). POEA is regulated separately under FFDCA and has been approved by the Agency. Additionally, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, registration process, EPA evaluates the potential risks posed by inert ingredients such as the POEA. The Agency requires a full disclosure of inert ingredients for each Roundup formulation to determine acute toxicity such as acute oral, eye, skin, inhalation, and dermal sensitization. The combined effects of active and inert ingredients on a product's acute toxicity properties are reviewed by the Agency and used to define the appropriate personal protective equipment (PPE) and precautionary statements for each pesticide end-use product label that will provide adequate protection to users.

2. *Genotoxicity (mutagencicty)—Comment:* The FR Notice describes assays showing that glyphosate does not cause genetic damage, but other studies have shown that both glyphosate and its commercial products are mutagenic, and the commercial products are more potent mutagens than glyphosate.

Agency response. The mutagenicity studies referred to by the commenters is the *Journal of Pesticide Reform* (JPR), a magazine produced by the Northwest Coalition for Alternatives to Pesticides (NCAP) based in Eugene, OR. JPR has compiled and updated fact sheets on a number of pest-control products, including glyphosate (the active ingredient in Roundup agricultural herbicides).

Based on the negative responses observed in well validated assays conducted according to the required test guidelines and in compliance with USEPA Good Laboratory Practice Standards, the Agency concluded that the active ingredient pesticide, glyphosate, is neither mutagenic or clastogenic.

Several studies have tested herbicide formulations, including Roundup, for mutagenic/genotoxic potential. Although positive responses have been reported, the testing systems used in the cited studies may not be adequate for regulatory purposes for one or more of the following reasons: (1) Un-validated test systems that do not have established predictability based on broad experience using substances of known positive and negative genotoxicity/ mutagenicity; (2) undocumented and uncharacterized test materials; (3) administered doses that cannot be correlated to expected exposures; (4) routes of exposure that vary from the required test protocols; (5) results that address endpoints which do not have a clear accepted relationship to human disease; and/or (6) deficient methodologies.

3. *Reproductive and developmental toxicity—Comment:* A study in Ontario found that father's (mostly farmers) use of glyphosate was associated with an increase in miscarriages and premature births in farm families. Laboratory studies on rats and rabbits have also demonstrated a number of effects from glyphosate on reproduction.

Agency response. Data from studies conducted according to accepted testing methods and reviewed by the Agency, demonstrate that glyphosate is not a

reproductive or developmental toxicant. Glyphosate was evaluated in two multigenerational rat reproduction studies and developmental toxicity studies in rats and rabbits. Results from these studies did not indicate any adverse effects on the animals' ability to mate, conceive, carry or deliver normal offspring. Based on the findings from developmental toxicity studies in rats and rabbits, it can be concluded that glyphosate does not produce birth defects and developmental toxicity is only seen at maternally toxic doses.

The developmental toxicity of the surfactant POEA has been evaluated and found not to be a teratogen or a developmental toxicant in rats. Subchronic toxicity studies with the surfactant and/or Roundup herbicide have also been conducted in rats, rabbits, and dogs. In these studies, gross and microscopic pathology examinations were conducted on several reproductive tissues including ovaries, uterus, testes, and epididymis. No developmental effects or changes in reproductive tissues were found in any of these evaluations. There is no evidence that the surfactant or Roundup herbicide adversely impacts reproductive function.

4. *Subchronic (medium-term) and chronic (long-term) toxicity studies on rats and mice—Comment.* Once again, studies (both subchronic and chronic) other than those cited by Monsanto reflect toxicity from glyphosate, and commercial products are more toxic than just glyphosate.

Agency response. The Agency has determined that the existing data base for glyphosate is adequate according to testing guideline requirements for a food-use registration. There is high confidence in the quality of the existing studies and the reliability of the toxicity endpoints identified for use in risk assessments; there are no data gaps. Based on evaluation of the existing glyphosate data base, the Agency has concluded that the use of glyphosate and glyphosate products do not pose unreasonable risks or adverse effects to humans.

The potential toxicity of POEA has been assessed in subchronic oral studies with rats and dogs. Roundup herbicide has also been evaluated for possible subchronic effects in an inhalation study with rats, a dermal study in rabbits, and an oral study with cattle. It was anticipated most observed effects would be related to the surface-active properties and associated irritation potential of surfactants. These studies confirm that irritation at the site of contact was the primary finding with the test material. In the oral studies conducted with POEA and Roundup, effects secondary to gastrointestinal irritation (emesis and diarrhea) were noted; decreased food consumption and decreased body weight gain. However, these effects were not dose-related in rats and dogs. In the study conducted with cattle in which slight decreases in body weight occurred, dosages of Roundup herbicide were 30 to 100 times greater than the dose typically applied to foliage for agricultural weed control purposes. There was no systemic toxicity in the inhalation and dermal studies conducted with Roundup. No indication of specific target organ toxicity was observed in any of the subchronic toxicity studies.

5. *Animal metabolism.* The Notice states:

> The qualitative nature of the residue in animals is adequately understood.

Comment: This is not true. There are a multitude of established effects on animals, including humans, and the mode of action is not understood at all. Roundup kills beneficial insects (parasitoid wasps, lacewings, ladybugs) and other arthropods that are important in humus production and soil aeration, and affect growth and survival of earthworms. Acute toxicities for fish LC_{50}, the lethal concentration killing 50% of a population of test animals) range from 2 ppm to 55 ppm and increase with increases in water temperature.

Agency response. Animal metabolism studies for pesticide active ingredients do not evaluate toxicological effects, but instead are designed to determine the fate of the molecule within a mammalian metabolic system. The animal metabolism data reviewed by the Agency for glyphosate are adequate and the qualitative nature of the residue in animals is understood.

Environmental consequences of pesticide use are considered in the FIFRA registration process. Based on the current toxicity data, application rates and observance of risk management measures for the active ingredient glyphosate, EPA has determined that the risks for birds, mammals, aquatic organisms, bees and invertebrates are minimal. Glyphosate is no more than slightly toxic to fish and wild birds, and practically non-toxic to aquatic invertebrate animals. There is a very low potential for the compound to build up in the tissues of aquatic invertebrates and other aquatic organisms such as fish. The Roundup formulation is moderately to slightly toxic to freshwater fish and aquatic invertebrate animals. Glyphosate is nontoxic to honeybees. This active ingredient pesticide as well as surfactants in the formulated products have no known effect on soil microorganisms. The reported contact lethal dose (LD_{50}) for earthworms in soil are greater than 5,000 parts per million (ppm) for both the glyphosate trimethylsulfonium salt and Roundup.

6. *Cancer.* Unit C.3.ii. of the Notice states:

> There is no evidence of carcinogenic potential.

Comment: This is false. A recent Swedish Study of hairy cell leukemia (HCL), a form of non-Hodgkin's lymphoma cancer, found that people who were occupationally exposed to glyphosate herbicides had a threefold higher risk of HCL. A similar study of people with non-Hodgkin's lymphoma found exposure to glyphosate was associated with an increase risk of about the same size.

Agency response. The commenters are referring to two epidemiology studies published by Sweden. This type of epidemiologic evaluation does not establish a definitive link to cancer. Furthermore, this information has limitations because it is based solely on unverified recollection of exposure to glyphosate-based herbicides.

The carcinogenic potential of glyphosate has been evaluated in acceptable studies conducted in rats and mice. In June of 1991, the Agency concluded, following a thorough review of all available toxicity data, that glyphosate should be classified in Category E--Evidence of Non-carcinogenicity in Humans. This cancer classification was based upon the observation of no treatment-related tumors at any dose level with glyphosate tested up to the limit in rats and up to dose levels higher than the limit dose in mice, and the lack of evidence of mutagenicity/genotoxicity for glyphosate.

C. Exposure and Risk Assessments

1. *Dietary exposure.* Tolerances have been established (40 CFR 180.364) for the residues of glyphosate in or on a variety of food and feed commodities. The petitioner proposes to add potassium salt to this list of acceptable salt forms to which the tolerances apply, and to amend or add a number of new animal feed tolerances and one food tolerance. Tolerances are also established for animal organs that may be consumed by humans (kidney at 4.0 ppm and liver at 0.5 ppm), and for poultry meat at 0.1 ppm, eggs at 0.05 ppm, and poultry meat by-products at 1.0 ppm, based on animal-feeding studies and reasonable worst-case livestock diets.

The Notice states:

This analysis showed that the existing livestock tolerances are sufficient for any additional dietary burden arising from the proposed feed tolerances.

Comment: It is not clear what analysis this statement is referring to. In any case, raising the tolerances in feed should result in new meat tolerance studies being done.

Agency response. EPA has conducted an analysis of the reasonable worst-case livestock diets, which include the additional dietary burden from the glyphosate feed tolerances proposed in the FR Notice. Adequate animal feeding studies are available for glyphosate in cattle, swine, and poultry. Based on the existing and proposed tolerances, the total estimated dietary burden derived from treated feed commodities (including those genetically altered to be tolerant to glyphosate) would not result in meat, milk, or egg residues that exceed currently established food tolerances on these commodities.

2. *Drinking water—Persistence in soil—Comment:* Glyphosate is acknowledged to be extremely persistent in the soil under typical application conditions. AMPA (the primary metabolite) is even more persistent than glyphosate. Studies in eight states found that the half-life in soil (the time required for half of the original concentration of a compound to break down or dissipate) was between 119 and 958 days. AMPA has been found in lettuce and barley planted a year after glyphosate treatment.

Agency response. Based on studies conducted both in the laboratory and the field, the Agency has determined that glyphosate is readily degraded by soil microbes to AMPA which is subsequently degraded to CO2. Data from field dissipation trials from eight sites show that the median half-life (DT50) for glyphosate applied at maximum use rates was 13.9 days with a range of 2.6 (Texas) to 140.6 (Iowa). The reported half-lives from the field studies conducted in the coldest climates, i.e., Minnesota, New York, and Iowa were longest at 28.7, 127.8, and 140.6 days, respectively, indicating that the rate of glyphosate degradation is somewhat slower in cooler climates compared to milder ones. Further degradation of AMPA to CO2 occurs at a slower rate than the initial degradation of glyphosate. Because of the strong binding of both glyphosate and AMPA to soil particles, there is very little uptake into plants of either glyphosate or AMPA from soil, even right after application of glyphosate. AMPA was found in only trace levels in lettuce and barley planted a year after application of glyphosate to soil. AMPA has been determined to not be of toxicological concern.

3. *Found in water*. The Notice states:

Glyphosate adsorbs strongly to soil and would not be expected to move vertically below the 6 inch soil layer.

Comment: This is a false assumption. Glyphosate can move into surface water when the soil particles to which it tends to bind are washed into streams or rivers. Glyphosate has been found in both ground and surface water, where it can be toxic to aquatic life for a time.

Agency response. The FR notice statement refers to behavior of glyphosate in soil and its potential for movement to ground water, not its movement into surface water. Glyphosate adsorbs strongly to soil particles, which limits its vertical movement in soil and makes contamination of ground water unlikely to occur.

Glyphosate can potentially occur in surface water from spray drift, runoff, soil particle movement, or by direct application, but at concentrations that are much lower than levels at which toxic effects to aquatic organisms may occur. The Agency has estimated glyphosate levels that could occur in surface water based on presently approved use patterns using computer-modeling methods. Based on toxicological data from acute and chronic tests on fish and other aquatic species, EPA has determined that the potential for environmental effects of glyphosate in surface water is minimal.

The Notice states:

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for glyphosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of glyphosate.

Comment: The Agency had better get monitoring exposure data for drinking water, for both glyphosate and for AMPA.

Agency response. In November 1999, the EPA Office of Water issued a report titled ''A Review of Contaminant Occurrence in Public Drinking Water Systems.'' The data in the report is further discussed in the report ''Occurrence Summary and Use Support Document for the Six-Year Review of National Primary Drinking Water Regulations'' (draft report issued in March 2002). The study is an analysis to date of the occurrence of contaminants in public water systems (PWSs). State data bases of compliance-monitoring data from PWSs were the primary data sources for the analysis. Glyphosate monitoring data of both surface water and ground water sources for 7,800 PWSs were included in the analysis. Occurrences of detectable levels of glyphosate in ground water or surface water were very infrequent. All detections of glyphosate were below 10% of the Maximum Contaminant Level (MCL), which is the health-based maximum permissible level of a contaminant in water that is delivered to any user of a PWS. Only 0.1% of the PWSs reported any detection of glyphosate at a level above 1% of the MCL. These monitoring results are consistent with the modeling predictions discussed above, and reinforce the Agency's conclusion that aggregate exposure to glyphosate via all exposure routes, including drinking water, will not exceed the Agency's level of concern (100% of the cPAD).

4. *Non-dietary exposure*. The Notice states:

iii. Based on the low acute toxicity and the lack of other toxicological concerns, exposures from residential uses (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets) of glyphosate are not expected to pose undue risks.

Comment: There are many toxicological concerns and in California, glyphosate exposure illness among agricultural and landscape workers is common with serious effects reported including blurred vision, peeling of skin, nausea, headache, vomiting, diarrhea, chest pain, dizziness, numbness. How does EPA define undue risks?

Agency response. Some glyphosate end-use products are assigned Toxicity Categories I and II for eye and dermal irritation because they contain POEA surfactants, which have been identified as eye and dermal irritants. For all such formulations, the Agency continues to recommend the addition of personal protective equipment (PPE) and precautionary statements appropriate for labeling of end-use products in Toxicity Categories I and II.

D. Cumulative Effects

The Notice states:

EPA does not have, at this time, available data to determine whether glyphosate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerances action, therefore, EPA has not assumed that glyphosate has a common mechanism of toxicity with other substances.

Comment: When the mode of action is not clearly understood, even more uncertainty exists regarding synergistic effects with other substances. Rather

than raising tolerances, EPA should be exercising the Precautionary Principle and lowering them.

Agency response. The herbicidal mode-of-action of glyphosate in plants is well-understood (see Unit A. Residue Chemistry, Agency response of this document) but is not relevant to the determination of whether it shares a common mechanism of toxicity with other substances. Glyphosate does not appear to produce a toxic metabolite that is also produced by other substances that could be grouped together for a cumulative risk assessment, thus at this time, EPA will not include glyphosate in such an assessment.

E. Safety Determination

U.S. population and infants and children—Comment: The mode of action of glyphosate is not understood, synergistic effects are not understood, and a multitude of studies indicate that glyphosate is toxic in all standard categories of toxicological testing. Again, rather than raising tolerances, EPA should be exercising the Precautionary Principle and lowering them.

Agency response: The herbicidal mode-of-action of glyphosate in plants is well-understood (see the previous discussion above) but is not relevant to the determination of whether it shares a common mechanism of toxicity with other substances. Glyphosate does not appear to produce a toxic metabolite that is also produced by other substances that could be grouped together for a cumulative risk assessment, thus at this time, EPA will not include glyphosate in such an assessment. In evaluating these tolerance petitions, EPA has concluded that the proposed tolerances meet the FFDCA standard of reasonable certainty of no harm. This standard requires consideration of aggregate exposure to glyphosate from existing uses as well as exposure from the new uses proposed in the petitions before EPA. EPA requires that toxicological tests conducted with individual active ingredients using validated testing methods be submitted and reviewed in support of its registration decisions. Results from a complete data base of acceptable studies conducted with glyphosate have demonstrated that adverse effects will not occur at expected exposure levels. The Agency is not aware of scientific evidence that demonstrates enhanced potency of glyphosate's toxicological effects that arise through synergistic mechanisms.

F. International Tolerances

Several maximum residue limits (MRLs) for glyphosate have been established by Codex in or on various commodities. The Codex MRL for rice grain is 0.1 ppm. The proposed rice grain tolerance of 15.0 ppm, is based on crop field trial data obtained using glyphosate-tolerant rice and therefore cannot be lowered to maintain harmonization with the Codex MRL of 0.1 ppm. (Unit F of the Notice). Also, the Codex MRL for grass hay is 50 ppm, and that proposed here is 300 ppm; the Codex MRL for field corn is 1 ppm, and that proposed here is 6 ppm and the same statement, that the tolerance cannot be lowered, applies.

Comment: Here is a great example of one of the many detrimental ramifications from the widespread use of GMO's. They drive up the levels of pesticide residues in crops for food and feed, while the majority of society is trying to avoid consumption of pesticides. It is unclear here, who has written this part of the FR Notice, EPA or Monsanto. The phrase, cannot be lowered is an ominous statement. If followed, it means that if a corporation benefits from commercializing a product, all other values and considerations must be cast aside.

Agency response. The rice grain tolerance of 15.0 ppm initially requested by Monsanto Company and cited in the notice of filing pesticide petition to establish a tolerance for glyphosate in or on food (April 17, 2002, 67 FR 18894) is not included in this tolerance petition. In addition, Monsanto Company has amended the tolerance petition by deleting the proposed tolerance increase to 6 ppm for wheat, grain and revising its Roundup UltraMax Herbicide label by removing all instructions related to a preharvest application of this product to Roundup Ready wheat. EPA has determined that the amended use instructions support the existing 5 ppm tolerance level for wheat, grain (40 CFR 180.364).

The pesticide petition process exists so that petitioners can request that EPA establish new food or feed tolerances, or increase existing tolerances, to accommodate new pesticide uses. Petitions are only filed when residue studies have demonstrated that food residues requiring tolerances may occur. Although EPA's approval of such petitions does authorize the potential for increased exposure levels, the existence of food tolerances is not indicative of significant consumer risk. Using worst-case assumptions that: (1) 100% of crops will be treated and (2) that residues will occur at tolerance levels in all cases, EPA has concluded that exposure to glyphosate from food, including all present and proposed tolerances, will utilize only 1.8% of the cPAD for the U.S. population, 3.8% of the cPAD for all infants less than 1 year old, and 3.6% of the cPAD for children (1 to 6 years old). Thus, the risk to human health does not exceed the Agency's level of concern (100% of the cPAD).

The phrase cannot be lowered indicates that glyphosate use patterns in the U.S. differ from those that have been considered by Codex, and therefore the new U.S. food and/or feed tolerances are not harmonized with established Codex MRLs. Codex procedures require that new pesticide uses and tolerances must first be approved by national governments before they can be considered by the Codex Committee on Pesticide Residues. As a result, differences between Codex MRLs and U.S. tolerances are anticipated as use patterns evolve. Codex uses the Periodic Review process to periodically update MRLs to reflect the modified use patterns.

G. Conclusions

Comment: In many parts of this FR Notice, it is not possible to tell who has written it, EPA or Monsanto. As a member of an organization working hard to promote an environmentally sound, economically viable, socially just and humane agriculture and food system in this country, I was expecting to see evidence of an agency working to protect human health and our environment, this is very disappointing. Furthermore, there is no consideration given here to the effects the increased use of this pesticide may have on the soil. Lab studies have demonstrated that glyphosate reduces nitrogen fixation associated with legumes and increases the susceptibility of crop plants to a number of diseases. Roundup is toxic to *mycorrhizal* fungi, with effects on some species observed at concentrations of 1 ppm, lower than those found in soil following typical applications.

Agency response. Publication of petitioner-generated summaries is dictated by the FFDCA, 21 U.S.C. 346a(d)(3). The Notice clearly indicates that the petitioner, Monsanto, has written the summary. However, much of this information can be found in the Agency's risk assessment document/supporting documentation for glyphosate. EPA has conducted a complete and thorough review of the available data for glyphosate. Based on the risk assessments conducted for glyphosate, the Agency determined that there is reasonable certainty that

exposure to glyphosate will not pose unreasonable risks or adverse effects to humans or the environment.

The Agency has received no reports indicating that the use of glyphosate adversely effects nitrogen fixation in legumes or that it increases the disease susceptibility of crops. These type of environmental considerations are more appropriately raised in connection with the FIFRA registration process.

H. Biotechnology Related Issues

Comment: Several comments were received in the public docket that expressed concern over the tolerance approvals for glyphosate that will directly support new uses in glyphosate-tolerant crops, namely wheat, rice and bentgrass. The list of commenters are as follows: Mark Trechock/Staff Director/ Dakota Resource Council, Annie Ray/ Oregon Rural Action, Helge Hellberg/ Marketing Director/California Certified Organic Farmers, Lauran Dundee/ Regional Outreach Coordinator/Partners for Global Justice and Sustainable Communities, Kevin L. Williams/Field Coordinator/Western Organization of Resource Councils, Suzin Kratina/Chair of the Food Safety Task Force/Northern Plains Resource Council, Harriet Ritter and Renata Brillinger.

Agency response. The rice grain tolerance of 15.0 ppm initially requested by Monsanto Company and cited in the Notice of Filing Pesticide Petition to establish a Tolerance for Glyphosate in or on Food (April 17, 2002, 67 FR 18894), is not included in this final rule.

Tolerance actions for glyphosate are considered independently of the other regulatory assessments that a new crop trait must pass before it can be commercialized. Three U.S. Federal agencies regulate crops incorporating traits derived from biotechnology. The Food and Drug Administration (FDA) has responsibility for evaluating the safety of crops derived through biotechnology for use as food and feed. The U.S. Department of Agriculture, Animal Plant Health Inspection Service (USDA APHIS) is responsible for agronomic characteristics and environmental impact. EPA is responsible for the assessment of the human health and environmental risk of pesticide products, including plant-incorporated pesticides, and their registration under FIFRA, as amended. Commercialization by Monsanto of additional glyphosate-tolerant crops, i.e., wheat, rice and bentgrass, cannot occur until such time as the USDA APHIS and the FDA have received and evaluated necessary data from the registrant and granted necessary approvals. As of 2002, Monsanto has submitted a petition to USDA APHIS for GM bentgrass.

Despite the separate nature of the evaluations and approvals, much closer communication has developed between the three agencies in recent years. In early 2001, EPA and USDA APHIS established an interagency work group for products derived from biotechnology. Through this joint working group, EPA consults on a stewardship plan for each new herbicide-tolerant crop that addresses the management of pest resistance and the potential for weedy volunteer crops in their herbicide-tolerant crops and in crop rotations. This stewardship plan is then incorporated into a full environmental impact assessment by USDA APHIS that addresses the potential for development of resistant weed populations through pollen flow, in addition to effects on non- target organisms and agricultural practices. EPA and USDA APHIS have established a strong working relationship through this joint review process that helps ensure that the concerns of both agencies are adequately addressed prior to final approval by either.

Based on the incomplete status of the interagency approval process discussed above, EPA has decided not to register the use of glyphosate in or on herbicide-tolerant wheat or herbicide-tolerant bentgrass at this time.

Some commenters express concern over the potential contamination of organic crops through pollen drift from herbicide-tolerance crop varieties that may be grown on near-by farms. The issue of organic operations in proximity to operations that employ methods that are prohibited under organic rules is discussed in the National Organic Program, Final Rule, available on the USDA Web site at: *http://www.ams.usda.gov/nop/nop2000/Final%20Rule/nopfinal.pdf*.

IV. Statutory Findings

The petition requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate, in or on animal feed, nongrass, group at 400 part per million (ppm), grass, forage, fodder and hay, group at 300 ppm, wheat, forage at 10 ppm, wheat, hay at 10 ppm, and adding the potassium salt of glyphosate to the tolerance expression.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

V. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of glyphosate on animal feed, nongrass, group at 400 ppm, grass, forage, fodder and hay, group at 300 ppm, wheat, forage at 10 ppm, and wheat, hay at 10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the acute toxic effects caused by glyphosate are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed in the following Table 2.

TABLE 1.—ACUTE TOXICITY OF GLYPHOSATE TECHNICAL

Guideline No.	Study Type	Results
870.1100	Acute oral	LD_{50} > 5,000 mg/kg Toxicity Category IV
870.1200	Acute dermal	LD_{50} > 5,000 mg/kg Toxicity Category IV
870.1300	Acute inhalation	The requirement for an acute inhalation LC_{50} study was waived
870.2400	Primary eye irritation	Corneal opacity or irritation clearing in 7 days or less Toxicity Category III
870.2500	Primary skin irritation	Mild or slight irritant Toxicity Category IV
870.2600	Dermal sensitization	Not a dermal sensitizer

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents - mouse	NOAEL = 1,500 mg/kg/day in males and females LOAEL = 4,500 mg/kg/day in males and females based on decreased body weight gain
870.3100	90–Day oral toxicity rodents - rat (range-finding)	NOAEL = < 50 mg/kg/day in males and females LOAEL = 50 mg/kg/day in males and females based on increased phosphorus and potassium values
870.3150	90–Day oral toxicity in rodents - rat (aminomethyl phosphoric acid - plant metabolite of glyphosate)	NOAEL = 400 mg/kg/day in males and females LOAEL = 1,200 mg/kg/day in males and females based on body weight loss and histopathological lesions of the urinary bladder.
870.3485	28–Day inhalation toxicity - rat (exposure; 6 hours/day, 5 days/week for 4 weeks)	NOAEL = 0.36 mg/L LOAEL = > 0.36 (HDT) mg/L, not established
870.3200	21-Day dermal toxicity - rabbit	NOAEL = 1,000 mg/kg/day in males and females LOAEL = 5,000 mg/kg/day based on slight erythema and edema on intact and abraded skin of both sexes, and decreased food consumption in females
870.3700	Prenatal developmental in rodents - rat	*Maternal* NOAEL = 1,000 mg/kg/day LOAEL = 3,500 mg/kg/day based on inactivity, mortality, stomach hemorrhages and reduced body weight gain *Developmental* NOAEL = 1,000 mg/kg/day LOAEL = 3,500 mg/kg/day based on increased incidence in the number of fetuses and litters with unossified sternebrae and decreased fetal body weight.

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in nonrodents - rabbit	*Maternal* NOAEL = 175 mg/kg/day LOAEL = 350 mg/kg/day based on mortality, diarrhea, soft stools, and nasal discharge. *Developmental* NOAEL = 350 mg/kg/day LOAEL = > 350 (HDT) mg/kg/day, not established
870.3800	Reproduction and fertility effects - rat (3-generation)	*Parental/Systemic* NOAEL = 30 mg/kg/day LOAEL = > 30 (HDT) mg/kg/day, not established *Reproductive* NOAEL = 30 mg/kg/day LOAEL = > 30 (HDT) mg/kg/day, not established *Offspring* NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on focal dilation of the kidney in male F3b pups
870.3800	Reproduction and fertility effects - rat (2-generation)	*Parental/Systemic* NOAEL = 500 mg/kg/day in males and females LOAEL = 1,500 mg/kg/day in males and females based on soft stools, decreased body weight gain and food consumption. Focal dilation of the kidney observed at 30 mg/kg/day in the 3-generation study was not observed at any dose level in this study. *Reproductive* NOAEL = > 1,500 (HDT) mg/kg/day in males and females LOAEL = > 1,500 (HDT) mg/kg/day in males and females, not established *Offspring* NOAEL = 500 mg/kg/day in males and females LOAEL = 1,500 mg/kg/day in males and females based on reduced pup weights during the second and third weeks of lactation
870.4100	Chronic toxicity dogs	NOAEL = 500 (HDT) mg/kg/day in males and females LOAEL = > 500 mg/kg/day in males and females, not established
870.4300	Chronic/carcinogenicity rats	NOAEL = 362 mg/kg/day in males LOAEL = 940 mg/kg/day in males based on decreased urinary pH, increased incidence of cataracts and lens abnormalities, and increased absolute and relative (to brain) liver weights NOAEL = 457 mg/kg/day in females LOAEL = 1,183 mg/kg/day in females based on decreased body weight gain No evidence of carcinogenicity

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL—Continued

Guideline No.	Study Type	Results
870.4300	Carcinogenicity mice	NOAEL = 750 mg/kg/day in males LOAEL = 4,500 mg/kg/day in males based on significant decreased body weight gain, hepatocyte necrosis, and interstitial nephritis NOAEL = 750 mg/kg/day in females LOAEL = 4,500 mg/kg/day in females based on significant decreased body weight gain, increased incidence of proximal tubule epithelial basophilia, and hypertrophy in the kidney of females No evidence of carcinogenicity
870.5100	Gene mutation assay in *S. typhimurium strains*	Negative. Non-mutagenic when tested up to 1,000 µg/plate, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537.
870.5100	Gene mutation assay in *E. coli* WP2hcrA and *S. typhimurium* strains	Negative for reverse gene mutation, both with and without S-9, up to 5,000 µg/plate (or cytotoxicity) with *E. coli* WP2hcrA and *S. typhimurium* TA98, TA100, TA1535, TA1537, and TA1538
870.5300	Gene mutation assay in Chinese hamster ovary (CHO) cells/HGPRT	Negative. Non-mutagenic at the HGPRT locus in Chinese hamster ovary cells tested up to cytotoxic concentrations or limit of solubility, in presence and absence of activation.
870.5385	Cytogenetics - *In vivo* bone marrow chromosomal aberration assay	Negative. Non-mutagenic in rat bone marrow chromosome assay up to 1,000 mg/kg in both sexes of Sprague Dawley rats
870.5550	Other mechanisms - *In vitro* Rec-Assay with *B. subtilis* H17 (rec+) and M45 (rec-)	There was no evidence of recombination in the rec-assay up to 2,000 µg/disk with *B. subtilis* H17 (rec+) and M45 (rec-)
870.6200	Acute neurotoxicity screening battery in rats	N/A
870.6200	Subchronic neurotoxicity screening battery in rats	N/A
870.6300	Developmental neurotoxicity in rats	N/A
870.7485	Metabolism and pharmacokinetics - rat	Absorption was 30-36% in males and females. Glyphosate was excreted unchanged in the feces and urine (97.5% minimum). The only metabolite present in the excreta was AMPA. Less than 1% of the absorbed dose remained in the carcass, primarily bone. Repeat dosing did not alter metabolism, distribution, and excretion.
870.7600	Dermal penetration	N/A

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is

routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for glyphosate used for human risk assessment is shown in the following Table 3.

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR GLYPHOSATE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk	Assessment Study and Toxicological Effects
Acute dietary (females 13-50 years old and general population)	None	None	An acute dietary endpoint was not selected for the general population or females 13-50, since an appropriate endpoint attributable to a single exposure was not identified in the toxicology data base
Chronic dietary (all populations)	NOAEL = 175 mg/kg/day UF = 100 Chronic RfD = 1.75 mg/kg/day	FQPA SF = 1 cPAD = cRfD ÷ FQPA SF = 1.75 mg/kg/day	Developmental toxicity study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Short-, and intermediate-term incidental, oral (Residential)	NOAEL = 175 mg/kg/day	LOC for MOE = 100	Developmental toxicity study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Short-, intermediate- and long-term dermal (1–30 days, 1–6 months, 6 months–lifetime) (Occupational/Residential)	None	None	Based on the systemic NOAEL of 1,000 mg/kg/day in the 21–day dermal toxicity study in rabbits, and the lack of concern for developmental and reproductive effects, the quantification of dermal risks is not required
Short-, intermediate- and long-term inhalation (1–30 days, 1–6 months, 6 months-lifetime) (Occupational/Residential)	None	None	Based on the systemic toxicity NOAEL of 0.36 mg/L (HDT) in the 28–day inhalation toxicity study in rats, and the physical characteristics of the technical (wetcake), the quantification of inhalation risks is not required
Cancer (oral, dermal, inhalation)	Cancer classification (Group E)	Risk Assessment not required	No evidence of carcinogenicity

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.364) for the residues of glyphosate, in or on a variety of raw agricultural commodities. The current proposal to establish glyphosate tolerances at 300 and 400 ppm for animal feed, nongrass, group (Crop Group 18) and grass, forage, fodder and hay, group (Crop Group 17), respectively, is not expected to result in an increase in the dietary burden for cattle, poultry, and hogs. Respective dietary burdens of 210 ppm and 220 ppm were recently estimated by the Agency for dairy and beef cattle, including a contribution from alfalfa hay as the roughage component of the diet with a tolerance of 400 ppm. Furthermore, no impact is expected on the dietary burden to poultry or hogs since grass forage and hay are not feed items for these livestock, and the contribution from alfalfa was already considered. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. A review of the toxicity data base, including the developmental toxicity studies in rats and rabbits, did not provide an endpoint that could be used to quantitate risk to the general population and to females 13–50 years old from a single-dose administration of glyphosate. Therefore, no acute dietary analysis was conducted for glyphosate.

ii. *Chronic exposure*. The glyphosate chronic dietary exposure analysis was conducted using the DEEM™ software Version 7.73, which incorporates consumption data from USDA's CSFII, 1989-1992. The 1989–92 data are based on the reported consumption of more than 10,000 individuals over 3 consecutive days, and therefore represent more than 30,000 unique person days of data. Foods as consumed (i.e., apple pie) are linked to raw agricultural commodities and their food forms (i.e., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM™ software. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic dietary exposure and risk assessments, an estimate of the residue level in each food or food-form (i.e., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD for chronic exposure. This procedure is performed for each population subgroup.

The Tier 1 chronic dietary exposure analysis for glyphosate is an upper bound estimate of chronic dietary exposure. The chronic dietary exposure analysis was performed for the general U.S. population and all population subgroups using DEEM™ default processing factors for rice and corn commodities, tolerance levels, and 100% crop treated data for the proposed commodities and all registered uses. For chronic dietary risk, the Agency's LOC is less than 100% cPAD. Dietary exposure estimates for representative population subgroups are presented in Table 4. The results of the chronic analysis indicate that the estimated chronic dietary risk as represented by the percent cPAD is below the Agency's LOC (100% cPAD) for the U.S. population and all population subgroups.

TABLE 4.—SUMMARY OF RESULTS FROM CHRONIC DEEM™ ANALYSIS OF GLYPHOSATE

Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. population (total)	0.031527	1.8
All Infants (< 1 year old)	0.062218	3.6
Children (1–6 years old)	0.068016	3.9
Children (7–12 years old)	0.045529	2.6
Females (13–50 years old)	0.023477	1.3
Males (13–19 years old)	0.031938	1.8
Males (20+ years old)	0.026745	1.5
Seniors (55+ years old)	0.022733	1.3

iii. *Cancer*. The HED Cancer Peer Review Committee classified glyphosate as a Group E chemical, negative for carcinogenicity in humans, based on the absence of evidence of carcinogenicity in male and female rats as well as in male and female mice.

iv. *Anticipated residue and percent crop treated information*. The Agency used tolerance levels and 100% percent crop treated (PCT) data for the proposed commodities and all registered uses.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for glyphosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of glyphosate.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental

concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and from residential uses. Since DWLOCs address total aggregate exposure to glyphosate, they are further discussed in the aggregate risk section E. (Aggregate Risks and Determination of Safety) of this Unit.

Based on the GENEEC and SCI-GROW models, the EECs of glyphosate for acute exposures are estimated to be 21 parts per billion (ppb) for surface water and 0.0038 ppb for ground water. The EECs for chronic exposures are estimated to be 0.83 ppb for surface water and 0.0038 ppb for ground water, based on glyphosate treatment crops. To estimate the possible concentration of glyphosate in surface water resulting from direct application to water, the Agency assumed application to a water body 6 feet deep. At an application rate of 3.75 lb acid equivalent (ae)/A, the estimated concentration is 230 ppb. Because the glyphosate water-application estimate is greater than the crop application estimate, 230 ppb is the appropriate value to use in the chronic risk estimate.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

i. *Non-occupational (recreational) exposures*. Glyphosate is currently registered for use on the following residential non-dietary sites: Recreational areas, including parks and golf courses for control of broadleaf weeds and grasses, and lakes and ponds, including reservoirs for control of nuisance aquatic weeds. Based on the registered uses, adult and child golfers are anticipated to have short-term post-application dermal exposure at golf courses. Swimmers (adults, children and toddlers) are anticipated to have short-term post-application dermal and incidental ingestion exposures. However, since the Agency did not select dermal endpoints, no post-application dermal assessment is included; only a post-application incidental ingestion exposure assessment (swimmers) is included. Risk estimates for incidental ingestion by swimmers (adults, children, and toddlers) ranged from 7,600 to 36,000. It should be noted however, that glyphosate is used for non-selective weed control on emerged aquatic weeds. In this use pattern, it is unlikely that swimmers would be present in waterbodies with floating weeds present. Thus, the inclusion of the swimmer incidental ingestion exposure assessment is considered by the Agency to be conservative. Table 5 presents a summary of assumptions used to estimate the exposure to adult and toddler child swimmers and the corresponding risk estimates.

TABLE 5.—ASSUMPTIONS AND RISK ESTIMATES FOR POST-APPLICATION SWIMMER EXPOSURE ASSESSMENTS FOR GLYPHOSATE, ISOPROPYLAMINE SALT

Exposure Scenario	AR1 (lb a.e./A)	Maximum Concentration in water (mg/L) [2]	Potential Dose Rate (PDR; oral mg/kg bw/day) [3]	Short-term MOE [4]
Incidental oral ingestion, adult-female	3.75	1.38	0.00493	36,000
Incidental oral, toddler			0.023	7,600

[1] Application rate from registered labels for aquatic weed control using glyphosate IPA salt (ex. label = EPA Reg. No. 524–343; max rate = 7.5 pints/A containing 4 lb ae glyphosate/gal. x 1 gal./4 pints = 3.75 lb ae/A.
[2] Maximum concentration in water (top 1 ft.) = 3.75 lb ae/A x 1A/43,560 ft^2 x 454,000 mg/lb x 1/ft x ft^3/28.32 L = 1.38 mg/L.
[3] PDR, incidental oral exposure = concentration, Cw (mg/L) x ingestion rate, IgR (L/hr) x exposure time, ET (hrs/d) x 1/BW (adult-female = 60 kg; toddler = 15 kg).
[4] MOE = NOAEL/PDR; short-term incidental oral NOAEL = 175 mg/kg bw/d; The LOC for adult females and toddlers for short-term, incidental oral exposures is MOEs < 100.

The MOEs presented in Table 5 for post-application exposure by swimmers to glyphosate in aquatic weed control applications are greater than 100 and do not exceed the Agency's LOC for short-term non-occupational (recreational) exposures (MOEs less than 100).

ii. *Residential exposures*. Glyphosate, isopropylamine salt is also registered for broadcast and spot treatments on home lawns and gardens by homeowners and by lawn care operators (LCOs). Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who apply products containing glyphosate (residential handlers). Additionally, based on the results of environmental fate studies, there is also a potential for short- and intermediate-term post-application dermal exposures by adults and toddlers and incidental ingestion exposures by toddlers. However, since the Agency did not select short- or intermediate-term dermal or inhalation endpoints, no residential handler or post-application dermal assessment is included; only a post-application toddler assessment for incidental ingestion exposures is included. Risk estimates for toddler post-application incidental ingestion exposures ranged from 7,200 to greater than 10^6. All recreational and residential exposures assessed do not exceed the Agency's level of concern (MOEs less than 100). Table 6 provides a summary of the short- and intermediate-term risk estimates for post-application incidental ingestion exposures to toddlers.

TABLE 6.—SUMMARY OF TODDLER INCIDENTAL INGESTION EXPOSURES AND RISK ESTIMATES FOR RESIDENTIAL USE OF GLYPHOSATE, ISOPROPYLAMINE SALT [1]

Activity	AR (lbs a.e./A) [2]	Residue Estimate [3]	PDR (mg/kg bw/d) [4]	Short-/Intermediate-term MOE [5]
Hand-to-mouth	1.62	DFR: 0.908 µg/cm^2	0.0242	7,200
Object-to-mouth		DFR: 3.63 µg/cm^2	0.00605	29,000
Soil ingestion		Soil residue: 12.2 µg/g soil	8.13 x 10^{-5}	> 10^6

[1] Sources: Standard Operating Procedures for Residential Exposure Assessments, Draft, December 17, 1997 and Exposure SAC Policy No. 11, February 22, 2001: Recommended Revisions to the SOPs for Residential Exposure.
[2] AR = maximum application rate on Roundup ProDry label (EPA Reg. No. 524–505) for residential lawn treatment.
[3] Residue estimates based on the following protocol from the Residential SOPs:
a. Hand-to-mouth DFR = 1.62 lb ae/A x 0.05 x (4.54 x 10^{-8} µg/lb ae) x (2.47 x 10^{-8} A/cm^2) = 0.908 g/cm^2.
b. Object-to-mouth DFR = 1.62 lb ae/A x 0.20 x (4.54 x 108 µg/lb ae) x (2.47 x 10^{-8} A/cm^2) = 3.63 µg/cm^2.
Soil Residue = 1.62 lb ae/A x fraction of residue in soil (100%)/cm x (4.54 x 10^8 µg/lb ae) x (2.47 x 10^{-8}A/cm2) x 0.67 cm^3/g= 12.2 µg/g soil.
[4] Potential Dose Rate (PDR; already normalized to body weight of toddler).
a. Hand-to-mouth PDR = (0.908 g/cm^2 x 0.50 x 20 cm^2/event x 20 events/hr x 10^{-3} mg/µg x 2 hrs/d)/15 kg = 0.0242 mg/kg bw/d.
Object-to-mouth PDR = (3.63 g/cm^2 x 25 cm^2/d x 10^{-3} mg/µg)/15 kg = 0.00605 mg/kg bw/d.
Soil Ingestion PDR = (12.2 µg/g soil x 100 mg soil/d x 10^{-6} g/µg)/15 kg = 8.13 x 10^{-5} mg/kg bw/d.
[5] MOE = NOAEL/PDR, where the short-term incidental oral NOAEL = 175 mg/kg/d the Agency's LOC is for MOEs < 100 (short-term residential).

All MOEs calculated for post-application toddler exposures do not exceed the Agency's level of concern for residential exposures (MOEs less than 100).

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether glyphosate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, glyphosate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that glyphosate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1.*In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* The toxicology data base for glyphosate is adequate according to the Subdivision F Guideline requirements for a food-use chemical. Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2-generation reproduction study in the rat. Based on the available data, the Agency determined that there is no evidence of either a quantitative or qualitative increased susceptibility following in utero glyphosate exposure to rats and rabbits, or following prenatal/postnatal exposure in the 2-generation reproduction study in rats.

3. *Conclusion.* There is a complete toxicity data base for glyphosate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency determined that the FQPA Safety Factor to protect infants and children can be removed (reduced from 10X to 1X) for all population subgroups and exposure scenarios because:

1. The toxicology data base is complete.

2. A developmental neurotoxicity study is not required.

3. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative

drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute aggregate risk (food + drinking water).* The Agency did not identify an appropriate acute dietary endpoint that is the result of a single-dose administration of glyphosate. Accordingly, glyphosate is not expected to pose an acute risk.

2. *Chronic aggregate risk (food + drinking water).* Using the exposure assumptions described in this unit for chronic exposure (tolerance level residues, DEEM™ default processing factors for rice and corn commodities, and 100% crop treated data for all proposed commodities and registered uses), EPA has concluded that exposure to glyphosate from food will utilize 1.8% of the cPAD for the U.S. population, 3.6% of the cPAD for [All Infants (less than 1 year old) and 3.9% of the cPAD for children 1–6 years old. The results of the chronic analysis (Table 4 in this unit) indicate that the chronic dietary risk estimates for the general U.S. population and all population subgroups associated with the existing and proposed uses of glyphosate do not exceed the Agency's LOC (less than 100% of the cPAD). Based on the use pattern, chronic residential exposure to residues of glyphosate is not expected. In addition, there is potential for chronic dietary exposure to glyphosate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 7 below:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO GLYPHOSATE

Scenario/Population Subgroup	cPAD, mg/kg/day	Chronic Food Exposure, mg/kg/day	Maximum Chronic Water Exposure [1], mg/kg/day	Ground Water EEC, ppb	Surface Water EEC, ppb	Chronic DWLOC [2], ppb
U.S. population	1.75	0.031527	1.718473	0.0038	230	60,000
All infants (< 1 year old)	1.75	0.062218	1.687782	0.0038	230	17,000
Children (1–6 years old)	1.75	0.068016	1.681984	0.0038	230	17,000
Children (7-12 years old)	1.75	0.045529	1.704471	0.0038	230	17,000
Females (13-50 years old)	1.75	0.023473	1.726527	0.0038	230	52,000
Males (13-19 years old)	1.75	0.031938	1.718062	0.0038	230	60,000
Males (20+ years old)	1.75	0.026745	1.723255	0.0038	230	60,000
Seniors (55+ years old)	1.75	0.022733	1.727267	0.0038	230	60,000

[1] Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM™ (mg/kg/day).
[2] The chronic DWLOCs were calculated as follows: DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption (L/day) x 0.001 mg/µg.

3. *Short-/intermediate-term aggregate risk (food + residential + water).* In aggregating short-/intermediate-term risk, HED considered background chronic dietary exposure (food + water) and short/intermediate-term incidental oral exposures (see Tables 6 and 7). Because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures (Table 7) exceeded the incidental oral exposure estimates from post-application swimmer exposures (Table 6), the Agency conducted this risk assessment using exposure estimates from just the worst-case situation. No attempt was made to combine exposures from the swimmer and residential turf scenarios due to the low probability of both occurring.

The total short-/intermediate-term food and residential aggregate MOEs are 1,800-2,300. As these MOEs are greater than 100, the short-/intermediate-term aggregate risk does not exceed the Agency's LOC. For surface water and ground water, the EECs of glyphosate are less than the DWLOCs for glyphosate in drinking water as a contribution to short-/intermediate-term aggregate exposure. Therefore, the Agency concludes with reasonable certainty that residues of glyphosate in drinking water do not contribute significantly to the short-/intermediate-term aggregate human health risk at the present time. Table 8 summarizes the short-/intermediate-term aggregate exposure to glyphosate residues.

TABLE 8.—SHORT/INTERMEDIATE-TERM AGGREGATE RISK AND DWLOC CALCULATIONS FOR EXPOSURE TO GLYPHOSATE RESIDUES

Population	Short-/Intermediate-Term Exposure Scenario				
	Aggregate MOE (food + residential) [1]	Aggregate Level of Concern (LOC) or Target MOE [2]	Surface Water EEC [3] (ppb)	Ground Water EEC [3] (ppb)	Short/Intermediate-Term DWLOC [4], (ppb)
All Infants (<1 year old)	1,900	100	230	0.0038	17,000
Children (1–6 years old)	1,800	100	230	0.0038	17,000
Children (7–12 years old)	2,300	100	230	0.0038	17,000

[1] Aggregate MOE = NOAEL ÷ (Average food exposure + Residential exposure).
[2] Basis for the target MOE: interspecies and intraspecies uncertainty factors totaling 100.
[3] The glyphosate use producing the highest level was used.
[4] DWLOC(µg/L or ppb) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ water consumption (L) x 10^{-3} mg/µg (10 kg body weight assumed).

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to glyphosate residues.

VI. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant and livestock commodities. These methods include GLC (Method I in Pesticides Analytical Manual (PAM) II; the limit of detection is 0.05 ppm) and HPLC with fluorometric detection. Use of the GLC method is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion in PAM II. A GC/MS method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL). Thus, adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in/on the nongrass animal feed crop group; the grass forage, fodder, and hay crop group; wheat forage and hay; and livestock commodities.

B. International Residue Limits

Codex and Mexican maximum residue limits (MRLs) are established for residues of glyphosate (glifosato) *per se* and Canadian MRLs are established for combined residues of glyphosate and AMPA in a variety of raw agricultural, processed, and animal commodities. Currently a relevant Codex MRL for hay or fodder (dry) of grasses is established at 50 ppm. No Canadian MRLs are established for any grass commodity. A Mexican MRL is established for pasture at 0.2 ppm. Because of the higher residue levels resulting from the proposed use pattern, harmonization of U.S. grass tolerances with existing Codex or Mexican MRLs is not possible.

For wheat-related commodities, relevant Codex MRLs exist for: wheat grain at 5 ppm; unprocessed wheat bran at 20 ppm; wheat flour at 0.5 ppm; wheat wholemeal at 5 ppm; and straw and fodder (dry) of cereal grains at 100 ppm. Canadian MRLs are established for: wheat at 5 ppm and wheat milling fractions (excluding flour) at 15 ppm. A Mexican MRL is established for wheat at 5 ppm. By maintaining the wheat, milling fractions (excluding flour) tolerance at 20 ppm, harmony with international tolerances for wheat processed fractions can be maintained.

There are currently no Codex or Canadian MRLs established for glyphosate for any nongrass animal feed items. A Mexican MRL is established for alfalfa at 200 ppm. Harmonization with this level is not possible due to the higher residue levels found in the submitted field trial studies.

C. Conditions

None.

VII. Conclusion

Therefore, the tolerance is established for residues of glyphosate, in or on animal feed, nongrass, group at 400 ppm and grass forage, fodder and hay, group at 300 ppm and the potassium salt of glyphosate is added to the tolerance expression. Based on the Agency's decision not to register tolerances for glyphosate use in or on herbicide-tolerant wheat, the current tolerances on wheat are not modified.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0232 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 26, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing

is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0232, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal

officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 18, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.364 is amended by revising the introductory text of paragraph (a) and alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) *General*. Tolerances are established for residues of glyphosate (N-phosphomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on the following food commodities:

Commodity	Parts per million
* *	* * *
Animal feed, nongrass, group	400
* *	* * *
Grass, forage, fodder and hay, group	300
* *	* * *

* * * * *

[FR Doc. 02–24488 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0199; FRL–7200–6]

Triticonazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1 *H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Aventis CropScience USA requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer Crop Science. Therefore, the registrant is now Bayer Crop Science.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0199, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0199 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller. mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*.You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://

Exhibit C

* * * * *

[FR Doc. 04–24926 Filed 11–9–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0323; FRL–7683–9]

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of glyphosate, N-(phosphonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on cotton, gin byproducts and cotton, undelinted seed. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective November 10, 2004. Objections and requests for hearings must be received on or before January 10, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0323. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James A.Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 18, 2004 (69 FR 51301) (FRL–7364–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0F6195, 1F6274, 2F6487, and 3F6570) by Monsanto Company, 600 13th St., NW., Suite 660, Washington, DC 20005. The petition requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate, N-(phosphonomethyl)glycine, in or on alfalfa seed at 0.5 parts per million (ppm) (PP 2F6487); increasing the current tolerance for cotton, gin byproducts from 100 ppm to 150 ppm (PP 3F6570); rice, bran at 30 ppm; rice, grain at 15 ppm; and rice, hulls at 25 ppm (PP 1F6274); wheat, forage at 10.0 ppm; wheat, hay at 10.0 ppm (PP 0F6195). Monsanto Company also proposed to revise the entry for grain, cereal group tolerance ''except rice'' to read as grain, cereal group 15 except barley, field corn, grain sorghum, oats, rice, and wheat at 0.1 ppm (PP 1F6274). Monsanto Company also amended PP 0F6195 to delete the proposal for wheat grain at 6 ppm that was announced in the **Federal Register** of April 17, 2002 (67 FR 18894) (FRL–6830–5). The notice stated that tolerances for alfalfa, rice, wheat, and cotton gin byproducts include both conventional and genetically altered crops.

The notice also proposed that the tolerances for alfalfa, forage at 175 ppm and alfalfa, hay at 400 ppm be deleted from § 180.364. Also proposed was to amend § 180.364 by replacing the current listing vegetable, legume, group 6 except soybean at 5.0 ppm with the current crop group pea and bean, dried and shelled, subgroup 6C at 5.0 ppm. That notice included a summary of the petition prepared by Monsanto Company, the registrant. One comment was received in response to the notice of filing from B. Sachau, 15 Elm St., Florham Park, NJ 07932. The commenter objected to allowing any tolerance, wavier, or exemption for glyphosate. The commenter also objected to animal testing and stated that a more reliable method of testing should be developed. This comment is discussed further in Unit V.

During the course of the review the Agency decided to correct the company address to read Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 20005. The Agency also determined the tolerance proposed for cotton, gin byproducts should be raised to 175 ppm and that the current tolerance for cotton, undelinted seed be increased to 35 ppm.

The Agency has determined that based on available data, the current tolerances for alfalfa, forage and alfalfa, hay are to be maintained and that the current listing for vegetable, legume,

group 6 except soybean at 5 ppm is correct; therefore, these proposed changes are not made at this time. Also, even though the proposed tolerances for alfalfa, seed; rice, bran; rice, grain; rice, hulls; wheat, forage; and wheat, hay are included in the risk assessment discussed in Units III.C., D., and E., these tolerances are not being issued at this time.

The Agency is also correcting the proposed tolerance expression to agree with the current tolerance expression by including references to the salts. Therefore, the tolerance expression is corrected to read: Tolerances are established for residues of glyphosate, N-(phosophonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on cotton, gin byproducts at 175 ppm and cotton, undelinted seed at 35 ppm.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of glyphosate, N-(phosophonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on cotton, gin byproducts at 175 ppm and cotton, undelinted seed at 35 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by glyphosate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or UFs may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children, primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for glyphosate used for human risk assessment is discussed in

Unit V.B. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.364) for the residues of glyphosate, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

A review of the toxicity database, including developmental toxicity studies in rats and rabbits, did not provide an endpoint that could be used to quantitate risk to the general population and to females 13–50 years old from a single-dose administration of glyphosate. Therefore, no acute dietary analysis was conducted for glyphosate.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues, DEEM default factors and 100% crop treated. PCT and/or anticipated residues were not used.

iii. *Cancer.* Glyphosate is classified as a Group E chemical, negative for carcinogenicity in humans, based on the absence of carcinogenicity in male and female rats as well as male and female mice.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for glyphosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of glyphosate.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration and Ground Water (SCI-GROW) model, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water in quantitative risk assessments. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to glyphosate they are further discussed in the aggregate risk sections, Unit III.E.

Based on the GENEEC, and SCI-GROW models, the EECs of glyphosate for acute exposures are estimated to be 21.0 parts per billion (ppb) for surface water and 0.0038 ppb for ground water. The EECs for chronic exposures are estimated to be 0.83 ppb for surface water. The EEC resulting from the registered use of direct glyphosate application to surface water is 230 ppb. Because the glyphosate water-application estimate is greater than the crop-application estimate, 230 ppb is the appropriate value to use in the chronic risk assessment. The EEC for chronic exposure in ground water is 0.0038 ppb.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

i. *Non-occupational (recreational) exposures.* Glyphosate is currently registered for use on the following residential non-dietary sites: Recreational areas, including parks and golf courses for control of broadleaf weeds and grasses, and lakes and pond, including reservoirs for control of nuisance aquatic weeds. Based on the registered uses, adult and child golfers are anticipated to have short-term post-application dermal exposure at golf courses. Swimmers (adults, children, and toddlers) are anticipated to have short-term post-application dermal and incidental ingestion exposures. However, since the Agency did not select dermal endpoints, no post-application dermal assessment was performed.

A post-application incidental ingestion exposure assessment for swimmers was performed. This assessment assumed 100% of applied concentration available at maximum application rate in the top one foot of water column; an ingestion rate of 0.05 Liter/hour (L/hr), and an exposure duration of 5 hrs/day (although a toddler is unlikely to be exposed for 5 hrs/day). Adult and toddler swimmers were included in this assessment as they are anticipated to represent the upper and lower bound of swimmer exposures. The respective body weights are 60 kilogram (kg) for adult-females (since NOAEL is based on developmental study) and 15 kg for toddlers. This exposure assessment is fully discussed in Unit V.C. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2). MOEs for incidental exposure for incidental ingestion by swimmers were 7,600 for toddler and to 36,000 for adult females and therefore, do not exceed the Agency's level of concern (LOC) for short-term non-occupational (recreational) exposures (MOEs of less than 100).

ii. *Residential exposures.* Glyphosate is also registered for broadcast and spot treatments on home lawns and gardens by homeowners and by lawn care operators (LCOs). Based on the registered residential use pattern, there is a potential for short-term dermal and inhalation exposures to homeowners who apply products containing

glyphosate (residential handlers). Additionally, based on the results of the environmental fate studies, there is a potential for incidental ingestion by toddlers. However, since the Agency did not select short- or intermediate-term dermal or inhalation endpoints, no residential handler or post-application dermal assessment was performed.

A post-application toddler assessment for incidental ingestion exposure assessment was performed. The *SOPs For Residential Exposure Assessments*, Draft, 17-DEC-1997 and Exposure Science Advisory Committee (ExpoSAC) Policy No. 11, 22-FEB-2001: *Recommended Revisions to the SOPs for Residential Exposure* were used to estimate post-application incidental ingestion exposures and risk estimates for toddlers. The following assumptions were used to assess exposures to toddlers after contact with treated lawns: Toddler body weight of 15 kg; toddler hand-surface area is 20 centimeter squared $(cm)^2$, and a toddler performs 20 hand-to-mouth events per hr for short-term exposures; exposure duration of 2 hrs per day; 5% of application rate represents fraction of glyphosate available for transfer to hands and a 50% saliva extraction factor for hand-to-mouth exposures; surface area of a object (for toddler object-to-mouth exposures; surface area of an object (for toddler object-to-mouth exposures) is approximately 25 cm^2; 20% of application rate available as dislodgeable residues for object-to-mouth exposures; 100% of application rate is avaible in the top 1 cm of soil for soil ingestion exposures; and that a toddler can ingest 100 milligram (mg) soil/day. This risk assessment is fully discussed in Unit V.C. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2). MOEs for toddler post-application incidental ingestion exposures were 7,200 for hand-to-mouth, 29,000 for object-to-mouth and greater than 10^6 for soil ingestion, and therefore, do not exceed the Agency's level of concern for residential exposures (MOEs) less than 100.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to glyphosate and any other substances and glyphosate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that glyphosate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Based on the acceptable developmental studies, the Agency has determined that there is no evidence of either a quantitative or qualitative increased susceptibility following *in utero* glyphosate exposure to rats or rabbits, or following prenatal/postnatal exposure in the 2-generation reproduction study in rats.

3. *Conclusion*. There is a complete toxicity database for glyphosate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The impact of glyphosate on the nervous system has not been specifically evaluated in neurotoxicity studies. However, there was no evidence of neurotoxicity seen in either acute, subchronic, chronic, or reproductive studies. and there are no concerns for potential developmental neurotoxicity. Therefore, neurotoxicity studies are not required for glyphosate. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because the toxicology database is complete; a developmental neurotoxicity study is not required; there is no evidence of quantitative or qualitative increased susceptibility of the young demonstrated in the prenatal developmental studies in rats or rabbits and pre-/postnatal reproduction study in rats; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposure for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of

exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Glyphosate is not expected to pose an acute risk because no toxicological endpoints attributable to a single exposure (dose), including maternal toxicity in developmental toxicity studies, were identified in the available data.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to glyphosate from food will utilize 2.2% of the cPAD for the U.S. population, 3.9% of the cPAD for all infants < 1 year old, and 5.4% of the cPAD for children 1–2 years old. Based the use pattern, chronic residential exposure to residues of glyphosate is not expected. In addition, there is potential for chronic dietary exposure to glyphosate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO GLYPHOSATE

Population subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	1.75	2.2	230	0.0038	60,000
All infants < 1 year old	1.75	3.9	230	0.0038	16,800
Children 1–2 years old	1.75	5.4	230	0.0038	16,600
Females 13–49 years old	1.75	1.7	230	0.0038	51,600
Youth 13–19 years old	1.75	2.1	230	0.0038	51,400
Adults 20–49 years old	1.75	1.9	230	0.0038	60,100

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for glyphosate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,800 for all infants < 1 year old, 1,500 for children 1–6 years old, and 2000 for children 7–12 years old. Because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures exceeded the incidental oral exposure from post-application swimmer exposures, the Agency conducted this risk assessment using exposure estimates from the worst case situation. No attempt was made to combine exposures from swimmer and residential turf scenarios due to the low probability of both occurring. See Tables 5 and 6 from the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2) for detailed discussion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of glyphosate in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO GLYPHOSATE

Population subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
All infants < 1 year old	1,800	100	230	0.0038	16,500
Children 1–6 years old	1,500	100	230	0.0038	16,300
Children 7–12 years old	2,000	100	230	0.0038	16,600

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for glyphosate.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,800 for all infants < 1 year old, 1,500 for children 1–6 years old, and 2,000 for

children 7–12 years old. Because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures exceeded the incidental oral exposure from post-application swimmer exposures, the Agency conducted this risk assessment using exposure estimates from the worst case situation. No attempt was made to combine exposures from swimmer and residential turf scenarios due to the low probability of both occurring. See Tables 5 and 6 from the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2) for detailed discussion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of glyphosate in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO GLYPHOSATE

Population subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
All infants < 1 year old	1,800	100	230	0.0038	16,500
Children 1–6 years old	1,500	100	230	0.0038	16,300
Children 7–12 years old	2,000	100	230	0.0038	16,600

5. *Aggregate cancer risk for U.S. population*. Glyphosate has no carcinogenic potential.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available for the enforcement of tolerances for glyphosate in plant and livestock commodities. These methods include gas liquid chromatography (GLC) (*Method I in Pesticides Analytical Manual* (PAM II)) and High Performance Liquid Chromatography (HPLC) with fluorometric detection. Use of GLC is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion into PAM II. A Gas Chromatography Spectrometry (GC/MS) method for glyphosate in crops has also been validated by EPA.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Codex and Mexican maximum residue levels (MRLS) are established for residues of glyphosate per se and Canadian MRLs are established for combined residues of glyphosate and aminomethylphosphonic acid (AMPA) in a variety of raw agricultural commodities. Codex MRLs exist for dry peas and dry beans at 5 ppm and 2 ppm, respectively. Canadian MRLs exist for peas, beans, and lentils at 5 ppm, 2 ppm, and 4 ppm, respectively. Mexican MRLs of 0.2 ppm exist for both peas and beans. Codex and Canadian MRLs for beans and lentils, and Mexican MRLs for peas and beans are lower then necessary to cover residues from the use patterns in the United States. The proposed U. S. tolerance for the crop group peas and beans, dried and shelled, except soybeans, is in agreement with the Codex and Canadian MRLs for dry peas and peas, respectively, and are necessary to cover use patterns in the United States.

Currently no Codex MRL for cotton, gin byproducts or cotton, undelinted seed are established.

C. Conditions

There are no conditions of registration for the establishment of tolerances on cotton, gin byproducts or cotton, undelinted seed.

V. Comments

One comment was received in response to the notice of filing from B. Sachau, 15 Elm St., Florham Park, NJ 07932. The commenter objected to the allowance of any tolerances, waiver, or exemption from tolerance for glyphosate because there are bad effects from glyphosate. The commenter also objected to animal testing, because testing on rabbit or dog constitutes animal abuse, and stated that a more reliable method of testing should be developed.

The comment contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate expose to glyphosate, including all anticipated dietary exposure and all other exposures for which the is reliable information.

Health Effects Guidelines (Series 870) recommends that dog or rabbit be used for various acute, subchronic, and longer term chronic, carcinogenic, developmental, and reproductive studies. Information derived from these tests serve to indicate the presence of possible hazards likely to arise from exposure to the test substance. Currently, there are not *in vitro* studies that can address the questions these studies answer. The EPA is currently working with the Interagency Coordinating Committee on the Validation or Alternative Methods (ICCVAM) to investigate alternative *in vitro* methods.

VI. Conclusion

Therefore, the tolerance is established for residues of glyphosate, N-(phosophonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on cotton, gin byproducts at 175 ppm and cotton, undelinted seed at 35 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA

procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0323 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 10, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0323, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule

does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 25, 2004.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.364, paragraph (a) is amended by:

■ i. Revising the chemical name ''(N-phosphomethyl)glycine)'' in the introductory text to read ''N-(phosphonomethyl)glycine.''

■ ii. Revising in the table the entries ''cotton, gin byproducts'' and ''cotton, undelinted seed'' to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cotton, gin byproducts	175
Cotton, undelinted seed	35
* * *	* *

* * * * *

[FR Doc. 04–25098 Filed 11–9–04; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF DEFENSE

48 CFR Parts 209 and 252

[DFARS Case 2003–D011]

Defense Federal Acquisition Regulation Supplement; Contractor Qualifications Relating to Contract Placement

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to delete text pertaining to contractor qualification requirements. This rule is a result of a transformation initiative undertaken by DoD to dramatically change the purpose and content of the DFARS.

DATES: *Effective Date:* November 10, 2004.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Schulze, Defense Acquisition Regulations Council, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0326; facsimile (703) 602–0350. Please cite DFARS Case 2003–D011.

SUPPLEMENTARY INFORMATION:

A. Background

DFARS Transformation is a major DoD initiative to dramatically change the purpose and content of the DFARS. The objective is to improve the efficiency and effectiveness of the acquisition process, while allowing the acquisition workforce the flexibility to innovate. The transformed DFARS will contain only requirements of law, DoD-wide policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant effect beyond the internal operating procedures of DoD or a significant cost or administrative impact on contractors or offerors. Additional information on the DFARS Transformation initiative is available at *http://www.acq.osd.mil/dpap/dfars/transf.htm.*

This final rule is a result of the DFARS Transformation initiative. The DFARS changes include—

- Deletion of text at DFARS 209.103, 209.103–70, and 252.209–7000 pertaining to obsolete Intermediate Range Nuclear Forces (INF) Treaty inspection requirements.
- Deletion of text at DFARS 209.106–1, 209.106–2, and 209.202 containing internal DoD procedures relating to requests for pre-award surveys and approval for use of product qualification requirements. This text has been relocated to the new DFARS companion resource, Procedures, Guidance, and Information (PGI), available at *http://www.acq.osd.mil/dpap/dars/pgi.*
- Deletion of unnecessary first article testing and approval requirements in DFARS subpart 209.3.

DoD published a proposed rule at 69 FR 8150 on February 23, 2004. DoD received no comments on the proposed rule. Therefore, DoD has adopted the proposed rule as a final rule. An additional change has been made at DFARS 209.202 to reflect the qualification requirements for aviation critical safety items added to the DFARS on September 17, 2004 (69 FR 55987).

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule deletes DFARS text that is obsolete, unnecessary, or procedural, but makes no significant change to contracting policy.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

Exhibit D

§ 180.275 Chlorothalonil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Brassica, head and stem, subgroup 5A	5.0
* * *	* *
Ginseng	4.0
Horseradish	4.0
Lentil	0.10
* * *	* *
Okra	6.0
* * *	* *
Rhubarb	4.0
* * *	* *
Vegetable, cucurbit, group 9	5.0
Vegetable, fruiting, group 8, except tomato	6.0
Yam, true	0.10

* * * * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) * * *

Commodity	Parts per million
* * *	* *
Persimmon	1.5

* * * * *

[FR Doc. E8–28597 Filed 12–2–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0147; FRL–8385–7]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes new tolerances for certain plant commodities and all animal commodities, and revises other tolerances for glyphosate and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate). These changes are detailed in Unit II of this document. E.I. DuPont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 3, 2008. Objections and requests for hearings must be received on or before February 2, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0147. All documents in the docket are listed in the docket index available at http://*www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at http:/ /*www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305–5704; e-mail address: *walters.vickie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at http:/ /*www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0147 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 2, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0147, by one of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the o*N*-line instructions for submitting comments.

Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26372) (FRL–8121– 5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7146) by E.I. DuPont de Nemours and Company, DuPont Crop Protection, Laurel Run Plaza, P.O. Box 80, Newark, DE 19714–0030. The petition requested that 40 CFR 180.364 be amended by establishing tolerances for combined residues of the herbicide glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate, *N*-acetyl-*N*-(phosphonomethyl)glycine resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate to Optimum™GAT™ soybeans in or on the food commodities: Cattle, kidney; cattle, liver; egg, goat, kidney; goat, liver; hog, kidney; hog, liver; horse, kidney; horse, liver; poultry, meat; poultry, meat byproducts; sheep, kidney; sheep, liver; soybean, forage; soybean, hay; soybean, hulls; and soybean, aspirated grain fractions at levels already established for glyphosate alone. That notice referenced a summary of the petition prepared by E.I. DuPont de Nemours and Company, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

DuPont has requested a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA'') for the preplant application of the herbicides glyphosate and pyrithiobac sodium to glyphosate–tolerant soybean. The petitioner is also working to commercialize a genetically modified soybean designated as Optimum™GAT™ soybeans. *N*-acetyl-glyphosate is produced when glyphosate is applied to Optimum™GAT™ soybeans. As a result the petitioner is requesting that the glyphosate tolerance expression be modified from glyphosate per se to the combined residues of glyphosate and *N*-acetyl-glyphosate. This petition was filed in conjunction with Dupont's this requested change to its FIFRA registration.

Based upon review of the data submitted in support of the petition, EPA has determined that the residues of concern in these commodities are glyphosate and *N*-acetyl-glyphosate. The current tolerance expression specifies residues of glyphosate (*N*(phosphonomethyl)glycine). To address that *N*-acetyl-glyphosate was the major residue in mature Optimum™GAT™ soybean forage, hay, and seed, the Agency concluded that it is necessary to include this compound in the tolerance expression. EPA is splitting current § 180.364(a) into paragraphs (a)(1) and (a)(2). Paragraph (a)(1) will include all of the commodities currently in paragraph (a), except for the animal commodities and the commodities grain, aspirated fractions; soybean, forage; soybean, hay; soybean, hulls; and soybean, seed, which EPA is transferring to new paragraph (a)(2). The tolerances in paragraph (a)(2) will cover application of glyphosate to non-genetically modified soybeans, genetically-modified soybeans currently in use, and Optimum™GAT™ soybeans. Note that based on the submitted residue data on application of glyphosate to Optimum™GAT™ soybeans, the numerical value of the current soybean and livestock tolerances do not need to be changed (only the tolerance expression is changing). Combined residues of glyphosate and *N*-acetyl-glyphosate in soybean commodities derived from glyphosate-treated Optimum™GAT™ soybeans and livestock commodities from animals which consume only glyphosate-treated Optimum™GAT™ soybeans will not exceed the existing tolerance level. Additionally, the change in tolerance expression will not affect the application of the tolerance to soybean commodities derived from glyphosate-treated non-genetically modified soybean and livestock commodities from animals which consumed only glyphosate-treated non-genetically modified soybean because these commodities will have only glyphosate per se residues, and not *N*-acetyl-glyphosate residues.

In the **Federal Register** of May 2, 2007 (72 FR 24188)(FRL–8122–8), the Agency published a final rule revising the tolerance expression for glyphosate to include the dimethylamine salt of glyphosate. Because there is a potential for soybeans to be treated with product containing the dimethylamine salt of glyphosate the Agency has determined that the dimethylamine salt of glyphosate should be added to the tolerance expression for paragraph (a)(2).

Based upon review of the soybean processing studies submitted supporting the petition, EPA has determined that the currently established tolerances for the commodities grain, aspirated fractions and soybean, hulls need to be increased to 310 ppm and 120 ppm, respectively. Currently established tolerance levels for all other commodities in this rule are supported by available data.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for the combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities cattle, meat byproducts at 5.0 ppm; egg at 0.05 ppm; goat, meat byproducts at 5.0 ppm; grain, aspirated fractions at 310 ppm; hog, meat byproducts at 5.0 ppm; horse, meat byproducts at 5.0 ppm; poultry, meat, at 4.0 ppm; poultry, meat byproducts at 1.0 ppm; sheep, meat byproducts at 5.0 ppm; soybean, seed at 20.0 ppm; soybean, forage at 100.0 ppm; soybean, hay at 200.0 ppm, and soybean, hulls at 120 ppm and soybean, seed at 20.0 ppm. EPA's assessment of exposures and risk associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by glyphosate and its metabolite *N*-acetyl-glyphosate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled Petition: 6F7146. Glyphosate-Isopropylammonium and Pyrithiobac Sodium. Human Health Risk Assessment for Application to Glyphosate Tolerant Soybean; pages 7–10 in docket ID number EPA– HQ–OPP–2007–0147 and identified as document EPA–HQ–OPP–2007– 0147–0007.

The toxicological profile of glyphosate is discussed in the risk assessment referenced earlier in this section and in the risk assessment referenced in the final rule published in the **Federal Register** of December 20, 2006 (71 FR 76180) (FRL–8105–9) which establishes tolerances for residues of glyphosate in or on noni at 0.20 ppm; pea, dry at 8.0 ppm; safflower at 85 ppm; sunflower at 85 ppm; and vegetable, legume group 6 except soybean and pea, dry at 5.0 ppm.

Toxicological endpoints and current risk assessments for glyphosate are discussed in the risk assessment referred to in the final rule published in the **Federal Register** of December 20, 2006 (71 FR 76180) (FRL–8105–9) which establishes tolerances for residues of glyphosate in or on noni at 0.20 ppm; pea, dry at 8.0 ppm; safflower at 85 ppm; sunflower at 85 ppm; and vegetable, legume group 6 except soybean and pea, dry at 5.0 ppm.

1. A summary of the data submitted in support of the metabolite *N*-acetyl-glyphosate is listed below. Refer to the risk assessment available in the public docket for this rule and identified above as document EPA–HQ–OPP–2007–0147–0007 for more information.

i. An acute oral toxicity study in rats with an Acute Oral LD_{50} greater than 5,000 milligrams/kilogram (mg/kg).

ii. A 90–day subchronic oral (feeding) study, in which no systemic toxicity was observed in male and female rats at doses up to 18,000 ppm (equal to 1157/1461 mg/kg/day in males/females, respectively).

iii. *N*-acetyl-glyphosate was negative for mutagenicity in a bacterial reverse mutation assay (Ames test), an *in vitro* chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, an *in vitro* Mammalian Cell Gene Mutation Assay in CHO cells and an *in vivo* cytogenetics (bone marrow) in mice, and a metabolism and pharmacokinetics study.

2. *N*-acetyl aminomethylphosphonic acid (*N*-acetyl-AMPA) was detected as one of the metabolites formed following oral administration of *N*-acetyl-glyphosate. It is not expected to be absorbed quickly from the gastrointestinal tract since it is a charged molecule at the physiological pH. *N*-acetyl-AMPA is expected to be less toxic than *N*-acetyl-glyphosate. Data submitted in support of this metabolite included the following:

i. An acute oral toxicity study with an LD_{50} of greater than 8,300 mg/kg.

ii. A bacterial reverse mutation assay (Ames test), in which *N*-acetyl-AMPA was not mutagenic when tested up to 5,000 microgram (µg)/plate in presence and absence of activation in *S. typhimurium* strains of TA98, TA 100, TA1535, TA1537, and in *Escheria coli* strain WP2uvrA.

iii. An *in vitro* Mammalian Chromosome Aberration Test in Human Perpherral Blood Lymphocytes, in which *N*-acetyl-AMPA was negative for the induction of structural and numerical chromosome aberrations in both the non-activated and the S9-activated test systems when tested up to 15.30 milligrams/milliliter (mg/ml).

iv. An *in vitro* Mammalian Cell Gene Mutation Test (CHO/HPRT) Test, in which *N*-acetyl-AMPA was not mutagenic at the HGPRT locus in Chinese hamster ovary cells tested up to 1,531 µg/ml in the presence and absence of metabolic activation.

v. An *in vivo* Mouse Bone Marrow Micronucleus Test, in which *N*-acetyl-AMPA resulted in no detections of chromosomal aberrations were detected in male and female mice at doses up to 2,000 mg/kg.

3. For the purpose of assessing the aggregate risk from glyphosate tolerances, EPA has assumed that *N*-acetyl-glyphosate is equally toxic to glyphosate. This conservative assumption is based on the structural similarity of *N*-acetyl-glyphosate with glyphosate; a structure activity relationships (SAR) analysis of *N*-acetyl-glyphosate with a lack or structural alerts for carcinogenicity, mutagenicity and endocrine effects; and toxicity data for *N*-acetyl-glyphosate showing low acute toxicity, low subchronic toxicity and lack of mutagenicity, In all probability, *N*-acetyl-glyphosate is of lower toxicity than glyphosate. For example, subchronic toxicity testing with glyphosate showed no systemic toxicity in male and female rats at doses up to 400 mg/kg/day in males and females. Subchronic testing with *N*-acetyl-glyphosate showed no systemic toxicity in male and female rats at doses up to 1157/1446 mg/kg/day in males/females, respectively.

The toxicity of *N*-acetyl-AMPA is considered low and of limited concern based on the available data described above, and lack of any structural alerts.

Amendment of the glyphosate soybean and meat and milk tolerances to include *N*-acetyl-glyphosate in the tolerance expression does not result in changes in the exposure or risk estimates reported in the previous risk assessments for the reasons listed below and fully discussed in the risk assessment referenced earlier in this section.

i. The Agency has determined that *N*-acetyl-glyphosate has no greater toxicity than glyphosate and probably is of lower toxicity.

ii. The numerical value of all but two food tolerances will remain the same.

iii. The most recent dietary analysis assumed tolerance level residues and, 100% crop treated.

iv. The estimate of glyphosate levels in drinking water is based on a glyphosate use involving direct application to water at 3.75 pounds active ingredient per acre. Use of glyphosate on glyphosate-resistant soybeans will not result in higher levels in drinking water.

v. Previously calculated dietary burdens to poultry were based on alfalfa meal (400 ppm tolerance) and soybeans hulls (100 ppm tolerance) as significant contributors to the diet. Based on the latest guidance, although soybean seed, meal, and hulls are feed to poultry, soybean hulls are is no longer considered a significant contributor to poultry diets. The previously calculated dietary burdens to hog were based on alfalfa meal and barley grain (20 ppm tolerance) being significant contributors to the diet. Soybean seed and meal are fed to hogs; however, the current action does not require an increase in tolerance for soybean seed or meal. Based on these complications, the Agency concludes that the application of glyphosate to Optimum™GAT™ soybean will not result in combined residues of glyphosate and *N*-acetyl-glyphosate (expressed as glyphosate) in poultry or hog commodities greater than the residues of glyphosate that result under the currently established glyphosate per se tolerances.

vi. Previously calculated dietary burdens to dairy or beef cattle were based on alfalfa hay (400 ppm tolerance) being the significant contributor to the diet. The Agency concludes that the consumption of glyphosate Optimum™GAT™ soybean will not result in combined residues of glyphosate and *N*-acetyl-glyphosate (expressed as glyphosate) in or on beef/dairy cattle commodities greater than the currently established glyphosate per se tolerances for the reasons below.

a. The high tolerance value for alfalfa hay (400 ppm) and alfalfa hay occupies 40% of the total beef/dairy cattle diet.

b. The soybean hull tolerance is only increasing from 100 to 120 ppm and soybean hulls will occupy at most 20% of the beef/dairy cattle dietary burdens.

c. Aspirated grain fractions occupy at most 5% of the beef cattle dietary burden and are not feed to dairy cattle.

Accordingly, based on the risk assessments discussed in the notice referenced above, EPA concludes that no harm will result to the general population and to infants and children from aggregate exposure to the combined residues of glyphosate and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate).

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography (HPLC) with tandem mass spectrometry (MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are Codex Maximum Residue Levels (MRL) established for glyphosate (sum of glyphosate and AMPA, expressed as glyphosate) on soybean, dry at 20 ppm; edible offal (mammalian) at 5 ppm; eggs at 0.05 ppm; poultry meat at 0.05 ppm and poultry, edible offal of at 0.5 ppm. Canadian MRLs are established for glyphosate including the metabolite aminomethylphosphonic acid (AMPA) on soybean seed at 20 ppm, kidney of cattle, goats, hogs, poultry and sheep at 2.0 ppm; and liver of cattle, goats, hogs, poultry, and sheep at 0.2 ppm. A Mexican MRL of 6 ppm is established for glyphosate. The glyphosate tolerances EPA is establishing in this action differ from the tolerance expression for the CODEX, Canadian or Mexican MRLs, due to the inclusion of *N*-acetyl-glyphosate in the expression. Additionally, the EPA tolerances differ from the CODEX and Canadian MRLs in that the EPA tolerances do not include AMPA in tolerance expression. At this time, harmonization between the U.S. tolerances and the CODEX, Canadian or Mexican MRLs can not be achieved because of the inclusion of *N*-acetyl-glyphosate in the EPA tolerances is necessary to support use patterns in the United States and EPA has concluded that AMPA should not be included in the tolerance expression because it is not toxicologically significant. The petitioner is seeking registration and amendment of the tolerance expressionin other countries. This may lead to harmonization between the U.S. tolerances and the CODEX, Canadian or Mexican MRLs.

C. Response to Comments

Three commenters submitted comments in response to the notice of filing. A summary of the comments and EPA's response follows.

1. *Comment*. One commenter does not believe that DuPont has submitted sufficient toxicological data to demonstrate that *N*-acetyl-glyphosate is not of toxicological concern and that submitted data did not support the claim of equivalent toxicity between glyphosate and *N*-acetyl-glyphosate. The commenter argued that the single acute toxicity EPA relied on actually suggests that *N*-acetyl-glyphosate is more toxic than glyphosate. This commenter also believes that reproductive, developmental, and chronic and carcinogenicity data on *N*-acetyl-glyphosate should be generated and analyzed.

Another commenter expressed concern that sufficient data may not have been submitted on the metabolite *N*-acetyl-glyphosate to satisfy the requirements for EPA to establish tolerances or to support the establishment of MRLs by other countries. The first commenter expressed a similar concern that submitted data failed to meet requirements of international authorities such as Joint FAO/WHO Meeting in Pesticide Residues (JMPR), particularly when compared to the extensive data bases required for other metabolites such as AMPA and *N*-acetyl-glufosinate.

Response. EPA does not agree with the contention that *N*-acetyl-glyphosate is more toxic than glyphosate. The Agency concluded that *N*-acetyl-glyphosate is not likely to be more toxic than glyphosate based on the available toxicity studies and Structure Activity Relationship (SAR). The available acute toxicity study with *N*-acetyl-glyphosate and glyphosate indicate low toxicity (Acute Oral LD_{50} was greater than 5,000 mg/kg bw). Both *N*-acetyl-glyphosate and glyphosate are placed in acute Tox Category IV. There was evidence of some mortality in an acute oral study with *N*-acetyl-glyphosate but not with glyphosate. However, the evidence from very high doses in this acute oral LD_{50} test suggesting that *N*-acetyl-glyphosate might be more toxic than glyphosate is outweighed by the results of subchronic tests with the two compounds. There was no evidence of systemic toxicity in 90–day dietary toxicity studying rats with *N*-acetyl-glyphosate conducted at well above the limit dose (18,000 PPM equal to 1,157/1,461 mg/kg/day in males and females, respectively). In a 90–day dietary toxicity study in rats with glyphosate at 0, 1,000, 5,000 or 20,000 ppm (equivalent to 0, 63, 317, or 1,267 mg/kg/day in males and 0, 84, 404, or 1,623 mg/kg/day in females), glyphosate caused increased serum phosphorus and potassium at all doses treated in both sexes and occurrence of high dose pancreatic lesions in males (effect was not evaluated at lower doses). Based on these findings systemic toxicity NOAEL for glyphosate can be considered as less than 1,000 ppm (equivalent to <63 mg/kg/day). Thus the subchronic study with *N*-acetyl glyphosate clearly indicates that it is less toxic than glyphosate. The available adequate battery of mutagenicity studies with *N*-acetyl glyphosate and glyphosate indicate that they are not mutagenic. The metabolism of *N*-acetyl glyphosate and glyphosate is well studied in rats. These studies indicate that both compounds are rapidly absorbed and excreted from the body and are not biosequestered. In fact, nearly all of the orally administered *N*-acetyl-glyphosate was excreted unchanged in the urine and feces. There is extensive database available on glyphosate, which indicate that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant. Based on its structural similarities with glyphosate and available data, it is reasonable to conclude that the *N*-acetyl-glyphosate is not likely to be more toxic than the parent. The Agency evaluated available information and data and concluded that additional data on *N*-acetyl-glyphosate was not needed based on the weight of evidence described above. In addition, Agency has accepted bridging data where evidence is clear in order to reduce the animal usage.

EPA also disagrees with the claim that EPA has insufficient data on *N*-acetyl-

glyphosate. EPA did review larger data sets on the metabolites AMPA and *N*-acetyl-glufosinate but these larger data sets were submitted voluntarily by pesticide registrants; EPA did not require these data to be submitted. EPA's decision to review all data that was submitted whether required or not (which is something the Agency does routinely) can not be converted into an EPA determination that such data would be required to make a safety finding for a similar pesticide metabolite. For the reasons expressed above, EPA concludes it has sufficient data on *N*-acetyl-glyphosate. For similar reasons, EPA also disagrees with the commenter's suggestion that because the Joint FAO/WHO Meeting in Pesticide Residues (JMPR) reviewed larger data sets on AMPA and *N*-acetyl-glufosinate, EPA's data set on *N*-acetyl-glyphosate must be deficient. The JMPR does not have any regulatory authority to require data and the commenters do not claim that JMPR defined the toxicological data needed to make the toxicity determinations with regard to AMPA and *N*-acetyl-glufosinate. The JMPR reviewed the data voluntarily submitted; it did not make a recommendation on the data necessary to make the needed toxicity evaluation.

2. *Comment*. One commenter argues that the higher residues of *N*-acetyl-glyphosate may be absorbed at a higher rate than glyphosate. Taking into consideration the increased absorption for *N*-acetyl-glyphosate compared to glyphosate are likely in meat, milk, poultry, and eggs due to the high values of *N*-acetyl-glyphosate that are likely in plants and the higher absorption in animals of *N*-acetyl-glyphosate (when compared to glyphosate). The commenter notes that Optimum™GAT™ soybeans were specifically engineered to convert *N*-acetyl-glyphosate and thus is likely to result in significant amounts of *N*-acetyl-glyphosate in soybeans. As to the higher absorption in animals, the commenter references a rat metabolism study and argues that indicates that higher absorption would occur in poultry and livestock that ingest residues of *N*-acetyl-glyphosate in feed and that the higher absorption would likely result in higher residues in meat, milk, and eggs when compared with glyphosate.

Response. As the commenter stated, the rat metabolism studies indicate that *N*-acetyl-glyphosate may be absorbed at a higher rate than glyphosate. Taking into consideration the increased absorption for *N*-acetyl-glyphosate, the previously calculated livestock diets (driven by 400 ppm alfalfa hay/meal tolerances), and the previously revised guidance concerning the construction of livestock diets (changes to the percent each food feedstuff contributes to a livestock diet, livestock diets are now constructed taking in to consideration nutritional requirements), it was concluded that higher livestock tolerances are not necessary. Note that the dietary analysis assumed tolerance level residue for the livestock commodities (i.e. assumes all of the commodities feed to livestock have tolerance level residues and all livestock commodities consumed by humans have tolerance level residues).

3. *Comment*. One commenter expressed concern that the petitioner had stated its intent to increase glyphosate spray rates or change spray timing and that residue data had not be submitted to reflect levels of *N*-acetyl-glyphosate under actual use conditions.

Response. The petitioner submitted several Optimum™GAT™ soybean magnitude-of-the-residue studies which monitored for residues of glyphosate and *N*-acetyl-glyphosate in forage and hay and soybean seed. (See document cited earlier in this unit for detailed discussion of these data). The Agency concluded that this data was acceptable and supported the proposed use pattern. The Agency also concluded that additional field trial data were not necessary and that the proposed tolerance levels discussed in Unit II of this document were acceptable. The Agency has not received an application requesting increased application rates or changes in application timing at this time. The Agency will reevaluate the need for additional magnitude-of-the-residue data if and when an application of this type is received.

4. *Comment*. A concern expressed by two of the three commenters was the possible amendment of FIFRA registration to allow higher application rates on soybeans of ALS inhibitor herbicides such as sulfonylureas already registered on soybeans or new uses of ALS inhibitor herbicides on soybeans. Such amended uses or new uses, the commenter urged, should be conditioned on the submission of additional residue data or consideration of possible effects to non-target plants and endangered species.

Response. The Agency has not received requests for increased use or new uses of ALS inhibitor pesticides on Optimum™GAT™ soybean seed to additional herbicides at this time. The pre-plant use of pyrithiobac sodium in soybeans remained unchanged for this action. However, as discussed on page 3 of the risk assessment referenced in Section III of this document, since ALS tolerance is conferred via modification of the endogenous ALS gene such that the plant is no longer sensitive (i.e. the tolerance is not conveyed via metabolism of the herbicide), the Agency's current view is that the nature/magnitude of residues submitted in support of registration of ALS-inhibiting herbicides to nontransgenic soybean are applicable for application of these compounds to Optimum™GAT™ soybean.

5. *Comment*. One commenter expressed a concern that the analytical method submitted may not enable simultaneous quantification of the combination of glyphosate, *N*-acetyl-glyphosate and aminomethylphosphonic acid (AMPA), all of which could be present in exported soybeans.

Response. Available information including Agency method trial confirms that proposed analytical method (high performance liquid chromatography (HPLC) with tandem mass spectrometry (MS/MS)) quantifies residues of glyphosate, *N*-acetyl-glyphosate, and AMPA in crops and animal commodities.

6. *Comment*. One commenter opposed the way the tolerance expression was written in the notice of filing and the fact that a new paragraph was being added to the tolerance expression allowing for duplicate listings of the same commodities dependent on genetic makeup.

Response. Based on the submitted comments and the available information the Agency has decided that 40 CFR 180.364(a) will be redesignated as paragraph (a)(1) and that the current listings from newly redesignated paragraph (a)(1) for soybean and animal commodities will be transferred to new paragraph (a)(2). The revised tolerance expression deletes any reference to genetic make up. See Unit II of this document for discussion.

7. *Comment*. One commenter expressed a concern that current EPA label policy allowing the use of general terminology such as ''glyphosate tolerant soybeans'' would permit use of any soybean seed that satisfies the general ''glyphosate tolerant'' criteria if crop seed such as Optimum™GAT™ soybean seed were commercially available, even if appropriate data have not been reviewed and tolerances granted.

Response. The EPA label policy is intended to allow the use of glyphosate on any approved glyphosate tolerant seed. The Agency does not regulate or approve the glyphosate tolerant seed, only the use of glyphosate on the crops grown from the glyphosate tolerant

seed. The approval of the seed itself is handled by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). Information on approval of the Optimum™GAT™ soybean seed is available in a notice published in the **Federal Register** of July 24, 2008 (73 FR 43203) which advised the public of their determination that a soybean line developed by Pioneer HI-Bred International, Inc., designated as transformation event 356043, which has been genetically engineered for tolerance to glyphosate and acetolactate synthase-inhibiting herbicides, is no longer considered a regulated article under their regulations governing the introduction of certain genetically engineered organisms, and the public docket established for that action by USDA/APHIS, which is available at *http://www.regulations.gov* and is identified as docket identification number APHIS–2007–019.

8. *Comment*. One commenter expressed a concern that Optimum™GAT™ soybeans are plants that have high levels of a new abnormal enzyme that creates new untested metabolites. The commenter referenced an article (Science, 21 May 2004, vol. 34 pp 1151–1154) which shows that the new ''shuffled enzyme'' (*N*-acetylate) can react with common amino acids L-aspartate, L-serine, phosphor-L-serine, L-threonine, L-glutamate, L-aspargine, and L-cysteine to form new *N*-acetylated versions of these common amino acids. The commenter stated that toxicology data may be necessary to address the safety of these *N*-acetylated metabolites.

Response. This issue concerns componets of the Optimum™GAT™ soybean and not residues of the pesticide glyphosate and is not relevant to EPA's determination of safety under section 408 of the FFDCA. However, similar comments were received and addressed by APHIS during the course of their review of the Optimum™GAT™ soybean seed which is fully discussed in the **Federal Register** notice of July 24, 2008 and the APHIS public docket referenced earlier in this unit. In summary APHIS reviewed available information toxicity data available for both the 356043 soybean seed and *N*-acetyl-L-aspartic acid (NAA) and determine that additional toxicological assessment was unwarranted. APHIS determined that quantification of other acetylated amino acids did not need to be measured based on the fact that the GAT4601 enzyme has different kinetic and specificity properties than the native enzymes from Bacillus licheniformis which have the ability to use additional amino acids as substrates under specific *in vitro* conditions. The study conducted with GAT4601 demonstrated the kinetic parameters could only be established for aspartate and glutamate. Additional information concerning this conclusion can be found in the APHIS public docket referenced earlier in this unit.

9. *Comment*. One commenter expressed concern that sufficient data may not have been submitted on the metabolite *N*-acetyl-glyphosate to satisfy the requirements for EPA to establish tolerances or to support the establishment of MRLs by other countries and Agencies. A second commenter expressed a similar concern that submitted data failed to meet requirements of international authorities such as Joint FAO/WHO Meeting in Pesticide Residues (JMPR), particularity when compared to the extensive databases required for other metabolites such as AMPA and *N*-acetyl-glufosinate.

Response. The Agency has determined that the submitted data discussed above and in the referenced risk assessments provided sufficient information for the Agency to make the required human safety determination required in the FFDCA and satisfy data requirements for establishment of tolerances and registration in the United States.

10. *Comment*. One commenter expressed concern that the proposed unilateral change to the glyphosate residue definition to include the new metabolite *N*-acetyl-glyphosate has significant potential to disrupt the international trade of soybeans for U.S. growers until the glyphosate residue definition is implemented globally. The commenter further noted that the data submitted to EPA may not be sufficient for other countries to modify their tolerance expressions.

Response. The petitioner submitted a summary of a metabolism study conducted with Optimum™GAT™ soybean. This study indicated that both glyphosate and *N*-acetyl-glyphosate were significant residues in/on Optimum™GAT™ soybean forage and straw. For mature Optimum™GAT™ soybean seed, only *N*-acetyl-glyphosate was a significant residue (glyphosate represented a minor component of the total residue). Since *N*-acetyl-glyphosate was the major residue in mature Optimum™GAT™ soybean forage, hay, and seed, EPA concluded that it is necessary to include this compound in the tolerance expression.

EPA believes that the new metabolite *N*-acetyl glyphosate is not likely to disrupt international trade of soybean for U.S. growers. DuPont is seeking registration in various countries. The Agency expects that the various countries will come to similar conclusion as the United States for Optimum™GAT™ soybean and amend their tolerance expressions which will alleviate the potential trade issue. The current analytical method would detect glyphosate, AMPA and *N*-acetyl glyphosate allowing enforcement of the tolerances in other countries. Growers in the United States have the option of growing conventional soybeans or other varieties of glyphosate tolerant seed until any trade issues in other countries with Optimum™GAT™ soybeans are resolved.

11. *Comment*. Several comments were received from a private citizen objecting to establishment of tolerances.

Response. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to the **Federal Register** of March 14, 2007 (72 FR 11784; FRL–8117–2) for the Agency's response to these objections. In addition the commenter noted that bees and turkey vultures are dying. These comments are not relevant to human safety determination which is the sole focus of tolerance actions under section 408 of the FFDCA. For informational purposes, EPA would note that pesticide effects on wildlife are addressed in the FIFRA registration process. In a honey bee contact test with glyphosate, mortality was low in all treatment levels. The results indicate that glyphosate is classified as practically nontoxic to honeybees. Although the Agency does not require testing on turkey buzzards specifically, the potential for avian mortality to glyphosate has been assessed using bobwhite quail acute oral LD_{50} study and bobwhite quail and mallard duck 8–day dietary LC_{50} studies. These data indicate that glyphosate is practically nontoxic to avian species on an acute oral basis and no more than slightly toxic on a subacute dietary basis. The potential effects to avian growth and reproduction from glyphosate have been assessed using avian reproduction studies with mallard duck and bobwhite quail. These data indicate that glyphosate is not expected to cause reproductive impairment. The commenter did not submit any information to support a revision of Agency conclusions.

V. Conclusion

Therefore, tolerances are established for combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the

isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities cattle, meat byproducts at 5.0 ppm; egg at 0.05 ppm; goat, meat byproducts at 5.0 ppm; grain, aspirated fractions at 310 ppm; hog, meat byproducts at 5.0 ppm; horse, meat byproducts at 5.0 ppm; poultry, meat, at 4.0 ppm; poultry, meat byproducts at 1.0 ppm; sheep, meat byproducts at 5.0 ppm; soybean, seed at 20.0 ppm; soybean, forage at 100.0 ppm; soybean, hay at 200.0 ppm, and soybean, hulls at 120 ppm as discussed in Unit II of this document.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 19, 2008.

Donald R. Stubbs,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.364 is amended as follows:

■ a. By removing the entries cattle, meat byproducts; egg; goat, meat byproducts; grain, aspirated fractions; hog, meat byproducts; horse, meat byproducts; poultry, meat; poultry, meat byproducts; sheep, meat byproducts; soybean, forage; soybean, hay; soybean, hulls; and soybean, seed from the table in paragraph (a).

■ b. By redesignating paragraph (a) introductory text and the remainder of the table as paragraph (a)(1) and by adding paragraph (a)(2) to read as follows:

§ 180.364 Glyphosate, Tolerance for residue.

(a) * * * (1) * * *

(2) Tolerances are established for combined residues of glyphosate, *N*-(phosphonomethyl)glycine and its metabolite *N*-acetyl-glyphosate (expressed as glyphosate) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on the food commodities:

Commodity	Parts per Million
Cattle, meat byproducts ...	5.0
Egg	0.05
Goat, meat byproducts	5.0
Grain aspirated fractions ..	310.0
Hog, meat byproducts	5.0
Horse, meat byproducts ...	5.0
Poultry, meat	4.0
Poultry, meat byproducts ..	1.0
Sheep, meat byproducts ..	5.0
Soybean, forage	100.0
Soybean, hay	200.0
Soybean, hulls	120.0
Soybean, seed	20.0

* * * * *

[FR Doc. E8–28571 Filed 12–2–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 404

[Docket No. 080227317–81455–02]

RIN 0648–AW44

Papahanaumokuakea Marine National Monument Proclamation Provisions

AGENCIES: National Oceanic and Atmospheric Administration (NOAA),

Exhibit E

timely notice of intent and extension request consistent with 98.234(f)(8)(ii) can automatically use best available monitoring method through June 30, 2012, for the specific parameters identified in their notification of intent and best available monitoring methods request regardless of whether the best available monitoring methods request is ultimately approved. Owners or operators that submit a notice of intent but do not follow up with a best available monitoring methods request by March 30, 2012 cannot use best available monitoring methods in 2012. For 2012, when an owner or operator has submitted a notice of intent and a subsequent best available monitoring method extension request, use of best available monitoring methods will be valid, upon approval by the Administrator, until the date indicated in the approval or until December 31, 2012, whichever is earlier. For reporting years after 2012, a new request to use best available monitoring methods must be submitted by June 30th of the year prior to the reporting year for which use of best available monitoring methods is sought.

* * * * *

[FR Doc. 2013–10184 Filed 4–30–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0132; FRL–9384–3]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glyphosate in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 1, 2013. Objections and requests for hearings must be received on or before July 1, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0132, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email address: *ertman.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0132 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 1, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0132, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 2, 2012 (77 FR 25954) (FRL–9346–1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E7979) by IR–4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.364 be amended by establishing tolerances for residues of the herbicide glyphosate *N*-(phosphonomethyl) glycine in or on the raw agricultural commodity teff, forage and teff, hay at 100 parts per million (ppm) and oilseed crops, group 20 at 40 ppm. The petition also requested amendments to the tolerances in 40 CFR 180.364 as follows: Vegetable, root and tuber, group 1, except sugar beet, from 0.2 ppm to 6.0 ppm; vegetable, bulb, group 3 at 0.2 ppm to

vegetable, bulb, group 3–07 at 0.2 ppm; okra at 0.5 ppm; vegetable, fruiting, group 8 at 0.1 ppm to vegetable, fruiting, group 8–10 at 0.1 ppm; fruit, citrus, group 10 at 0.5 ppm to fruit, citrus, group 10–10 at 0.5 ppm; fruit, pome, group 11 at 0.2 ppm to fruit, pome, group 11–10 at 0.2 ppm; cranberry, grape, juneberry, kiwifruit, lingonberry, salal, strawberry, and berry group 13 at 0.2 ppm to berry and small fruit, group 13–07 at 0.2 ppm. That document referenced a summary of the petition prepared by Monsanto, the registrant, which is available in the docket at *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities as well as the crops for which tolerances are being established. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for glyphosate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glyphosate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). A second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, and a lowest-observed-adverse-effect level (LOAEL) was identified at 20,000 ppm (approximately 940 milligram/kilogram/day (mg/kg/day)) based on decreased body-weight gains in females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in mice or rats. In a chronic toxicity study in dogs, no systemic effects were found in all examined parameters.

There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in an older 3-generation reproductive study on rats at the 30-mg/kg/day level (highest dose tested (HDT)); however, a 2-generation reproductive study on rats did not observe the same effect at the 1,500 mg/kg/day level (HDT), nor were any adverse reproductive effects observed at any dose level. A clear NOAEL was established and the chronic reference dose (cRfD) was set at a level well below this effect. Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate.

Neurotoxicity screening battery tests and an immunotoxicity study have been submitted to the Agency. Given the timing of the submission of these studies, the Agency has conducted preliminary reviews of these studies. The preliminary reviews show no effects up to the HDT for both the acute and subchronic durations for the neurotoxicity studies and no effects up to the HDT in the immunotoxicity study. EPA does not believe that further review will result in different conclusions concerning the neurotoxic or immunotoxic potential of glyphosate.

Specific information on the studies received and the nature of the adverse effects caused by glyphosate as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled ''Glyphosate. Section 3 Registration Concerning the Application of Glyphosate to Carrots, Sweet Potato, Teff, and Oilseeds (Crop Group (CG) 20) and to Update the CG Definitions for Bulb Vegetable (CG 3–07), Fruiting Vegetable (CG 8–10), Citrus Fruit (CG 10–10), Pome Fruit (CG 11–10), and Berry (CG 13–07). Human-Health Risk Assessment'' on pp. 26–28 in docket ID number EPA–HQ–OPP–2012–0132.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a RfD—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for glyphosate used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 8, 2011 (76 FR 19701) (FRL–8866–8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to glyphosate, EPA considered exposure under the petitioned-for tolerances as well as all existing

glyphosate tolerances in 40 CFR 180.364. EPA assessed dietary exposures from glyphosate in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for glyphosate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for both proposed and existing commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that glyphosate does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for glyphosate. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used both a screening level water exposure model (surface water) as well as monitoring data (ground water) in the dietary exposure analysis and risk assessment for glyphosate in drinking water. The simulation model takes into account data on the physical, chemical, and fate/transport characteristics of glyphosate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and monitoring data from the National Water-Quality Assessment Program (NAWQA), the estimated drinking water concentrations (EDWCs) of glyphosate for chronic exposures are estimated to be 8.11 parts per billion (ppb) for surface water and 2.03 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 8.11 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Glyphosate is currently registered for the following uses that could result in residential exposures: Turf (including golf courses and residential lawns) and for aquatic application. EPA assessed residential exposure using the following assumptions:

Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). However, since short- and intermediate-term dermal or inhalation endpoints were not selected, a quantitative exposure risk assessment was not completed.

Based on the registered use patterns, children 1–2 years old may have short-term post-application incidental oral exposures from hand-to-mouth behavior on treated lawns and swimmers (adults and children 3–6 years old) may have short-term post-application incidental oral exposures from aquatic uses. Based on the soil half-life for glyphosate, intermediate-term soil ingestion was also considered for children 1<2 years old. The incidental oral scenarios for the turf assessment (i.e., hand-to-mouth, object-to-mouth, and soil ingestion) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios would be overly conservative because of the conservative nature of each individual assessment. Therefore, none of the incidental oral scenarios were combined.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found glyphosate to share a common mechanism of toxicity with any other substances, and glyphosate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that glyphosate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in an older 3-generation reproductive study on rats at the 30-mg/kg/day level (HDT); however, a 2-generation reproductive study on rats did not observe the same effect at the 1,500 mg/kg/day level (HDT), nor were any adverse reproductive effects observed at any dose level. A clear NOAEL was established and the cRfD was set at a level well below this effect. Therefore, the endpoints selected for risk assessment are protective of the effects seen in the 3-generation rat reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for glyphosate is complete.

ii. There is no indication that glyphosate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. As discussed in Unit III.D.2., there is no evidence that glyphosate results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the surface water modeling used to assess exposure to glyphosate in drinking water. EPA used similarly conservative assumptions to assess post-application incidental oral exposure of children. These assessments will not underestimate the exposure and risks posed by glyphosate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, glypyhosate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to glyphosate from food and water will utilize 13% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of glyphosate is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to glyphosate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,000 for the general U.S. population and 450 for children 1–2 years old. Because EPA's level of concern for glyphosate is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for uses that could result in intermediate-term residential exposure to children 1–2 years old, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to glyphosate.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 770 for children 1–2 years old, the population subgroup of concern. Because EPA's level of concern for glyphosate is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, glyphosate is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for glyphosate in or on cotton seed at 40 ppm, sunflower seed at 7 ppm, and rape seed at 20 ppm. The MRL for cotton seed is the same as the oilseed crop group tolerance and the MRL for rape seed is the same as the canola seed tolerance being established by this document. Based on the oilseed residue data, harmonization with the Codex sunflower seed tolerance is not possible.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the petitioned-for tolerances as follows:

The proposed increase in tolerance for vegetables, root and tuber, group 1, except sugar beet from 0.2 ppm to 6 ppm cannot be done at this time due to inadequate residue data. Instead, the Agency is establishing individual tolerances for carrot at 5.0 ppm and sweet potato at 3.0 ppm and modifying the existing tolerance on vegetables, root and tuber, group 1, except sugar beet at 0.20 ppm to read as ''vegetables, root and tuber, group 1, except sugar beet, carrot, and sweet potato.''

The petition requested a tolerance at 40 ppm on the oilseed group 20. In order to maintain harmonization with both Canada and Codex the Agency is establishing a tolerance on the oilseed crop group 20, except canola at 40 ppm and is maintaining the existing canola seed tolerance at 20 ppm.

The petition requested that the current tolerance for vegetable, fruiting, group 8 be updated to the new vegetable, fruiting, group 8–10. Okra is part of the new crop group, however,

and the currently established tolerance in or on crop group 8 is 0.1 ppm, whereas the okra tolerance is 0.5 ppm. Due to this difference, the Agency is updating crop group 8 to read ''vegetable, fruiting, group 8–10, except okra'' and maintaining the existing okra tolerance at 0.5 ppm.

Lastly, several of the tolerance values on the crop group conversions are being revised to reflect Agency policy concerning significant figures.

V. Conclusion

Therefore, tolerances are established for residues of glyphosate *N*-(phosphonomethyl) glycine in or on the raw agricultural commodity teff, forage at 100 ppm; teff, hay at 100 ppm; oilseeds, group 20, except canola at 40 ppm; vegetable, root and tuber, group 1, except carrot, sweet potato, and sugar beet at 0.20 ppm; carrot at 5.0 ppm; sweet potato at 3.0 ppm; vegetable, bulb, group 3–07 at 0.20 ppm; vegetable, fruiting, group 8–10 (except okra) at 0.10 ppm; fruit, citrus, group 10–10 at 0.50 ppm; fruit, pome, group 11–10 at 0.20 ppm; and berry and small fruit, group 13–07 at 0.20 ppm.

In addition, due to the establishment of the tolerances in this document, the following tolerances are being removed as unnecessary: Vegetables, root and tuber, crop group 1, except sugar beet; vegetable, bulb, group 3; vegetable, fruiting, group 8; fruit, citrus, group 10; fruit, pome, group 11; berry group 13; borage, seed; cotton, undelinted seed; crambe, seed; flax, meal; flax, seed; jojoba seed; lesquerella, seed; meadowfoam, seed; mustard seed; rapeseed, seed; safflower, seed; sesame, seed; sunflower, seed; cranberry; grape; juneberry; kiwifruit; lingonberry; salal; and strawberry.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 19, 2013.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.364:

■ a. Add alphabetically to the table in paragraph (a)(1) the following commodities.

■ b. Remove from the table in paragraph (a)(1), the commodities berry group 13; borage, seed; cotton, undelinted seed; crambe, seed; cranberry; flax, meal; flax, seed; fruit, citrus, group 10; fruit, pome, group 11; grape; jojoba seed; juneberry; kiwifruit; lesquerella, seed; lingonberry; meadowfoam, seed; mustard seed; rapeseed, seed; safflower, seed; salal; sesame, seed; strawberry; sunflower, seed; vegetable, bulb, group 3; vegetable, fruiting, group 8; vegetable, root and tuber, group 1, except sugar beet.

The additions read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) General. (1) * * *

Commodity	Parts per million
* * * * *	
Berry and small fruit, group 13–07	0.20
* * * * *	
Carrot	5.0
* * * * *	
Fruit, citrus, group 10–10	0.50
Fruit, pome, group 11–10	0.20
* * * * *	
Oilseeds, group 20, except canola	40
* * * * *	
Sweet potato	3.0
* * * * *	
Teff, forage	100
* * * * *	
Teff, hay	100

Commodity	Parts per million
* * * * *	
Vegetable, bulb, group 3–07	0.20
* * * * *	
Vegetable, fruiting, group 8–10 (except okra)	0.10

Commodity	Parts per million
* * * * *	
Vegetables, root and tuber, group 1, except carrot, sweet potato, and sugar beet	0.20
* * * * *	

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[FR Doc. 2013–10316 Filed 4–30–13; 8:45 am]

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Exhibit F

Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the Senate Committee on Agriculture, Nutrition, & Forestry, 114th Congress (2015) (statements of Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs, and Dr. Ronald E. Kleinman, Physician in Chief at Massachusetts General Hospital for Children, can be viewed at http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4 (at time stamps 55:05 – 56:20 and 2:39:28 – 2:40:01 respectively)